Proposed Re-evaluation Decision PRVD2011-14

Chlorothalonil

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the fungicide chlorothalonil, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing chlorothalonil in Canada.

An evaluation of available scientific information found that products containing chlorothalonil do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of chlorothalonil uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects all end-use products containing chlorothalonil registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for chlorothalonil and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of chlorothalonil.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, presents the details of the re-evaluation activities and program structure. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Given the outcome of foreign reviews, updated human health and environmental risk assessments and a review of the chemistry of Canadian products, the PMRA is proposing a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of chlorothalonil. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Chlorothalonil?

Chlorothalonil is a fungicide that is used to control fungal foliar disease of greenhouse (celery seedbed only) and field-grown crops [asparagus, blueberry, carrot, celery, chickpea, cole crops, cranberry, cucurbit, dry pea, evening primrose, ginseng, lentil, onion (dry bulb, green), parsnip, potato, strawberry, stone fruits, sweet corn, tomato, wheat], mushrooms, turf (specifically sod farms, and golf greens, tees and fairways), field-grown and greenhouse ornamentals and conifers, and is registered to control mildew in paints. Chlorothalonil is applied using either groundboom, airblast, backpack or aerial spray equipment, by farm workers. It can also be applied through the irrigation equipment in cranberry bogs and in mushroom houses using central or portable tanks for drench treatment. To control mildew in paints, chlorothalonil can be applied as a powder during the pigment grinding operation of the manufacturing process or applied as an aqueous dispersion during the pigment grinding operation, during or after letdown, or post-added to the finished product.

Health Considerations

Can Approved Uses of Chlorothalonil Affect Human Health?

Chlorothalonil is unlikely to affect your health when used according to the revised label directions.

People could be exposed to chlorothalonil by consuming food and water, through residential exposure (for example, golf courses and treated paint), while working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Chlorothalonil is currently registered in Canada for use on asparagus, blueberry, cherry, chickpea, carrot, celery, cranberry, cole crops, cucurbits, evening primrose, ginseng, lentils, mushroom, nectarine, onions, parsnip, peach, peas (dry), potato, strawberry, sweet corn, tomato and wheat, and could be used in other countries on crops that are imported into Canada. MRLs established for chlorothalonil are listed in Appendix VI. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

Environmental Considerations

What Happens When Chlorothalonil Is Introduced Into the Environment?

Chlorothalonil poses a potential risk to aquatic organisms, therefore additional risk reduction measures need to be observed.

When applied in the Canadian environment chlorothalonil is expected to be non-persistent in soil. Chlorothalonil is immobile in most soils and has a low potential to leach to groundwater. The major transformation product SDS-3701, however, is persistent in soil and has a potential to leach in some soils. Chlorothalonil may enter aquatic environments via spray drift and run-off. Once in the aquatic environment chlorothalonil is not persistent in surface waters and is expected to bind strongly to suspended particles and to partition into sediment. Residues of chlorothalonil have been detected in surface waters in sub-arctic and arctic lakes which show that it is subject to long range transport to remote regions.

The use of chlorothalonil is not expected to present a risk to terrestrial organisms including earthworms, bees, non-target plants, birds and small wild mammals. The major transformation product SDS-3701 is more toxic than chlorothalonil to birds and mammals, however, it is also not expected to present a risk to these organisms following applications of chlorothalonil in Canada.

In the aquatic environment chlorothalonil may pose a risk to some non-target aquatic organisms (particularly fish) as a result of spray-drift and run-off. In order to minimize the potential exposure to aquatic organisms, strips of land between the site of application and the aquatic areas (buffer zones) will be left unsprayed. The width of these buffer zones will be specified on the product label.

Several fish kill incidents associated with run-off of chlorothalonil residues have been reported in Canada and the U.S.A.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of chlorothalonil, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect workers
- A restricted-entry interval to protect workers re-entering treated sites;
- A statement restricting entry into treated areas for use on turf (including golf greens, tees and fairways);
- A restriction of the number of applications per floral production cycle on greenhouse cut flowers; and
- A reduction of maximum application rates on golf courses.

Environment

- Additional advisory label statements to reduce potential surface water contamination;
- Buffer zones to protect non-target aquatic organisms; and
- Changes to maximum application rate or number of yearly applications.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on chlorothalonil, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Chlorothalonil is a broad-spectrum, non-systemic fungicide. It belongs to FRAC Resistance Management Group M5. It is a multi-site inhibitor affecting various enzymes and other metabolic processes in Fungi. It inhibits spore germination, and is toxic to fungal cell membranes. The exact mechanism of action is complex, and involves conjugation with and depletion of fungal thiol compounds, leading to disruption of glycolysis and energy production.

Following the re-evaluation announcement for chlorothalonil, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial end-use products in Canada. As of March 17, 2011 there are no domestic class products containing chlorothalonil registered for use in Canada.

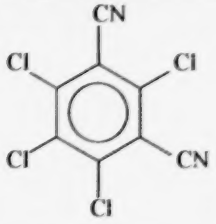
For the human-health portion of the re-evaluation of products containing chlorothalonil, the PMRA used recent assessments of chlorothalonil from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for chlorothalonil, dated April 1999, the USEPA Federal Register final rule, dated March 4, 2009, and related documents (Docket folder 2007-1106) for chlorothalonil to establish specific tolerances, as well as other information on the regulatory status of chlorothalonil in the United States can be found on the USEPA Pesticide Registration Status page at www.regulations.gov.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity

Table 1 Identity of the Technical Grade Active Ingredient

Common name			Chlorothalonil
Function			Fungicide
Chemical family			Chloronitrile
Chemical name			
	1	International Union of Pure and Applied Chemistry (IUPAC)	Tetrachloroisophtalonitrile
	2	Chemical Abstracts Service (CAS)	2,4,5,6-tetrachloro-1,3-benzenedicarbonitrile
CAS Registry Number			1897-45-6
Molecular formula			$C_8Cl_4N_2$

Common name	Chlorothalonil
Structural formula	
Molecular weight	265.93 amu

2.2 Physical and Chemical Properties

Table 2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	5.7×10^{-7} mm Hg
UV–visible spectrum	Minimal absorption above 350 nm
Solubility in water	0.81 mg/L
***n*-Octanol–water partition coefficient**	Log K_{ow} = 2.88
Dissociation constant	Does not dissociate under environmental conditions.

2.3 Impurities of Concern in the Technical Grade Active Ingredient

The following impurities of toxicological and environmental concern have been shown to be present in the technical grade chlorothalonil.

- Hexachlorobenzene (HCB)—detected at levels of up to 30 ppm
- Decachlorobiphenyl (DCB) —detected at levels of up to 15 ppm
- Chlorinated dioxins and furans—detected at levels of up to 0.16 ppb

Based on the manufacturing process, the impurities of toxicological and environmental concern pentachlorobenzene (QCB) and tetrachlorobenzene (TCB) are expected to be present in technical grade chlorothalonil.

Other contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

Hexachlorobenzene, decachlorobiphenyl, pentachlorobenzene, tetrachlorobenzene, chlorinated dioxins and furans expected to be present in the chlorothalonil technical grade active ingredients are classified as Toxic Substances Management Policy (TSMP) Track 1 contaminants. TSMP Track 1 contaminants are managed in accordance with the PMRA's strategy to prevent or minimize releases into the environment, with the ultimate goal of virtual elimination, as described under Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy* (see Section 5.1).

To ensure that PMRA has current information on Track 1 contaminants in pesticide products, new batch analyses are required for Track 1 contaminants with data >10 years old (QCB, TCB and dioxins/furans) (see Appendix I).

2.4 Description of Registered Chlorothalonil Uses in Canada

Chlorothalonil is a broad-spectrum, non-systemic fungicide. It is registered in Canada to control fungal foliar diseases of greenhouse (celery only) and field-grown crops [asparagus, blueberry, carrot, celery, chickpea, cole crops, cranberry, cucurbit, dry pea, evening primrose, ginseng, lentil, onion (dry bulb, green), parsnip, potato, strawberry, stone fruits, sweet corn, tomato, wheat], mushrooms, turf (specifically sod farms, and golf greens, tees and fairways), field-grown and greenhouse ornamentals, conifers and to control mildew in paints. Chlorothalonil is applied throughout the growing season, depending on the crop. Chlorothalonil is applied at a frequency of one to twelve applications per year, or "as needed", depending on the use, with the highest single application rates registered for golf courses (25.0 kg a.i./ha) and mushroom houses (127 g a.i./m^2). The agricultural and ornamental end-use products are formulated as emulsifiable concentrates, suspensions or dry flowables (water dispersible granules) and are applied using either groundboom, airblast, backpack or aerial spray equipment. End-use products can also be applied through the irrigation equipment in cranberry bogs and in mushroom houses using central or portable tanks for drench treatment.

Chlorothalonil is also registered for use as a material preservative. To control mildew in paints, chlorothalonil can be applied as a powder during the pigment grinding operation of the manufacturing process or applied as an active aqueous dispersion during the pigment grinding operation, during or after letdown or post-added to the finished product.

Although no domestic class products are registered in Canada, the general public may be exposed to residues of chlorothalonil through its use on golf courses or by applying paint containing chlorothalonil. Chlorothalonil is not registered for use around homes or other residential areas such as parks, school grounds and playing fields.

The American and Canadian use patterns were compared. Formulations of Canadian end-use products are encompassed by those registered in the United States. The Canadian use sites which are reflected in the USEPA documents include turf, ornamentals, paint and many of the vegetable and fruit crops, with the exception of evening primrose, dry peas and wheat. Canadian application rates are encompassed by the rates used in the USEPA risk assessments, with the exception of maximum rates for use on ornamental turf (including golf greens, tees and

fairways), and in mushroom houses. However, the Canadian registrant of chlorothalonil products registered for turf uses has agreed to reduce the maximum application rate for fairways, tees and greens to rates which are encompassed by the use rate used in the USEPA risk assessments for turf. Based on this comparison of use patterns, it was concluded that the USEPA RED for chlorothalonil and the Federal Register documents and related documents for chlorothalonil are an adequate basis for the assessment of risks to human health from the registered uses of this chemical in Canada.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation of chlorothalonil. Appendix II lists all chlorothalonil products that are registered as of 15 December 2010, under the authority of the *Pest Control Products Act*.

Improvements to product labels are required. The PMRA is proposing that product labels be amended to include complete application instructions reflecting the instructions provided in Appendix XI. The proposed label amendments are outlined in Appendix X.

2.4.1 Value

Chlorothalonil is a protectant contact fungicide with multi-site mode of action belonging to resistance management group M5. It is one of the most widely used broad-spectrum fungicides in Canada. As of March 17, 2010 there were 3 technical, and 28 commercial class end-use products registered in Canada. All labelled uses are supported by the technical registrant. End-use products containing chlorothalonil encompass one of the broadest ranges of label uses of any fungicide registered in Canada. It is used to control a broad spectrum of economically important plant diseases on a wide variety of crops and to control organisms that cause paint to deteriorate. Chlorothalonil remains a key fungicide for sustainable pest management and Integrated Pest Management on several important crops and diseases. To date there are no recorded incidences of resistance, despite a long history of use against high risk diseases, due to its multi-site mode of action. When used in rotation, chlorothalonil helps manage the development of fungicide resistance to many older, as well as newer lower risk fungicides.

3.0 Impact on Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to chlorothalonil may occur through consumption of food and water, through residential exposure (for example, golf courses, treated paint), while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

Chlorothalonil was classified as a "likely to be a human carcinogen by all routes of exposure" by the USEPA. At the time of the 2008 Human-Health Risk Assessment, the USEPA concluded that the margin of exposure approach could be supported for chlorothalonil cancer risk assessments.

For the re-evaluation of chlorothalonil, a linear approach using a cancer potency factor (Q_1*) was selected by the PMRA to estimate cancer risk from the use of this chemical in Canada. On this basis, only risk estimates using this approach are reported in this document.

The USEPA's toxicological endpoints for assessing risk to human health in their 2008 assessment are summarized in Appendix III. The USEPA's toxicological endpoints for cancer risks for chlorothalonil in the 1999 RED are summarized in Appendix IV.

3.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure. This is compared to a target margin of exposure incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated margin of exposure is less than the target margin of exposure, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

In the case where evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor (Q_1*) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk below 1 in 10^{-5} in worker populations is generally considered acceptable.

Workers can be exposed to chlorothalonil when mixing, loading or applying the pesticide, or when entering a treated site to conduct activities such as scouting and/or handling of treated crops or applying treated paint.

3.1.1 Mixer/Loader/Applicator Exposure and Risk

The 2008 USEPA Human-Health Risk Assessment did not cover all Canadian occupational exposure scenarios. Therefore, short- and intermediate-term inhalation (non-cancer) risk assessments were conducted by the PMRA, using the exposure assessments conducted in the 1999 RED and the inhalation endpoints identified by the USEPA in their 2008 assessment. Quantification of risk from short- and intermediate-term dermal exposure to chlorothalonil was not required by the USEPA in their 2008 assessment, because no systemic toxicity was observed in a dermal toxicity study in rats at doses up to 600 mg/kg/day and there were no developmental or neurotoxicity concerns; therefore, occupational risk was not assessed by the PMRA for this route of exposure. Long-term exposure of occupational handlers is not expected to occur in Canada.

Among the scenarios assessed in the RED, the following were considered relevant to the Canadian situation:

- Mixing/loading liquid flowable (open pour);
- Mixing/loading dry flowable (open pour);
- Application by air;
- Application by ground-boom (open cab);
- Application by airblast (open cab);
- Application by specialty air-assisted equipment to golf courses (open cab);
- Mixing/loading/application – backpack sprayer in a greenhouse;
- Mixing/loading/application – backpack sprayer outdoors;
- Mixing/loading/application – handgun sprayer using water dispersible granules;
- Mixing/loading/application – high pressure handwand;
- Application – indoor painting (latex) using airless sprayer;
- Application – outdoor painting (alkyd) using airless sprayer; and
- Application – outdoor painting (latex) using airless sprayer.

Handler exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED), as well as chlorothalonil specific monitoring studies. It was assumed that handlers wore baseline personal protective equipment (long-sleeved shirt and long pants) and that mixer/loaders also wore chemical-resistant gloves. Scenarios using a backpack sprayer in a greenhouse and using a high pressure handwand also assumed that a respirator was worn in addition to baseline personnel protective equipment and gloves. Numerous combinations of application rate and area treated daily were assessed. For aerial, chemigation and groundboom mixer/loader and applicator scenarios, maximum chlorothalonil application rates ranged from 2.5 to 14 kg a.i./ha with an area treated per day ranging from 8 to 400 hectares depending on the scenario. Backpack and handgun sprayer scenarios were based on a maximum application rate of 4.7 kg a.i./ha with 0.8 hectare treated per day. Paint scenarios ranged from an application rate of 5.8 g a.i./L for latex paints up to 13 g a.i./L for outdoor use of alkyd paints with the assumption that a maximum of 150 litres can be applied per day using an airless sprayer.

Results indicated that occupational exposures and risks were not of concern, with the exception of painting indoors with latex paint using an airless sprayer while wearing baseline personnel protective equipment.

In the 1999 RED, the USEPA reported Q_1^* carcinogenic risk estimates ranged from 1×10^{-8} to 1×10^{-5} and were not of concern for all occupational exposure scenarios relevant to Canada, including greenhouse uses. Using the Q_1^* value selected in the 1999 RED, the PMRA also conducted a cancer risk assessment for handlers exposed to chlorothalonil from the use of this chemical in mushroom houses. Cancer risk estimates ranged from 5×10^{-8} to 1×10^{-7} and were not of concern.

The RED and 2008 USEPA risk assessments adequately addressed exposure scenarios associated with the use of products containing chlorothalonil in Canada, with the exception of the maximum application rates for use on turf and in mushroom houses. Canadian registrants have agreed to reduce the maximum application rates on turf to a level which is covered by the USEPA assessments. Based on PMRA risks assessments currently on file and on additional risk assessments conducted by the PMRA, the mushroom use in Canada remains acceptable provided that the personal protective equipment, including a full face respirator, currently required on Canadian labels are worn.

Adding chlorothalonil to paint during the manufacturing process was also not specifically covered in the chlorothalonil RED. A risk assessment was conducted by the PMRA using the inhalation endpoint selected by the USEPA for their 2008 assessment, exposure values from the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study, and assuming that workers wore a long-sleeved shirt, long pants and chemical-resistant gloves. Results indicated that short- and intermediate-term inhalation exposure was not of concern.

Based on the above and on the acute inhalation toxicity of the technical grade chlorothalonil, it is proposed that painters using airless sprayers indoors, handlers in enclosed spaces (for example, greenhouses, mushroom houses, paint manufacturing facilities) and handlers using a high-pressure handwand be required to wear a respirator. It is proposed that all other handlers be required to wear a long-sleeved shirt, long pants and chemical-resistant gloves. In addition, because technical grade chlorothalonil is a severe eye irritant, it is proposed that all handlers wear protective eyewear. Several chlorothalonil end-use product labels include eye irritation warning statements on the primary display panel, while this warning is located in the Precautions section for other product labels. For consistency, the PMRA is proposing the requirement of an eye irritation warning statement on the primary panel of all end-use products containing chlorothalonil. The proposed label amendments are listed in Appendix X.

The requirement of efficacy data confirming that the proposed new rates of chlorothalonil will provide control of specific diseases on golf course turf, specifically, data demonstrating control of helminthosporium leaf spot or brown patch, is proposed. Appendix I lists all data requirements.

3.1.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considered exposures to workers entering treated sites. Based on chlorothalonil's use pattern, workers could be exposed to residues after the product is applied.

The USEPA determined in both the 1999 RED and the 2008 Human-Health Risk Assessment that postapplication inhalation exposure for outdoor uses would be negligible based on the fact that sprays will likely have dried if the restricted-entry interval (REI) required on American labels is followed, and based on the low vapour pressure of chlorothalonil. The USEPA did not identify a short- or intermediate-term dermal endpoint of concern in their 2008 assessment; therefore, occupational postapplication risk was not assessed for this route of exposure. Long-term postapplication exposure was not expected based on the American use pattern. In the 1999 RED, the USEPA reported acceptable Q_1* carcinogenic risk estimates ranging from $1 \times 10\text{-}^{11}$ to 1×10^{-5} for all postapplication scenarios.

The USEPA assessments addressed exposure scenarios associated with the Canadian uses of chlorothalonil, with the following exceptions: 1) non-cancer risks for long-term exposure of workers re-entering treated greenhouses where ornamentals are grown, and 2) cancer risks for workers re-entering treated greenhouses and mushroom houses after multiple chlorothalonil applications. Conclusions derived from the RED are considered to be applicable to the Canadian situation.

The PMRA conducted additional risk assessments for Canadian postapplication exposure scenarios not covered by the USEPA assessments. Chlorothalonil is expected to have low volatility based on its vapour pressure. On this basis, postapplication exposure to chlorothalonil residues in greenhouses and mushroom houses is expected to occur mainly through the dermal route, and inhalation exposure and risk were not assessed. The PMRA conducted long-term postapplication dermal exposure and risk (non-cancer) assessments for greenhouse ornamental uses, and assessed cancer risks to re-entering treated greenhouses and mushroom houses, using endpoints identified in the 1999 RED (see Appendix V). In the absence of data, the dissipation of residues is assumed to be zero in greenhouses and mushroom houses. Risk assessments for celery seedbeds and mushrooms were conducted using the maximum Canadian application rates per production cycle (18.9 kg a.i./ha and 190 g a.i./100 m^2, respectively). Based on current Canadian labels, chlorothalonil can be used weekly at a rate of up to 4.75 kg a.i./ha, as needed on greenhouse ornamentals. Risk assessments assuming an accumulation of residues after each application were conducted in order to determine the maximum number of applications at the maximum single application rate that can be allowed on greenhouse ornamentals without resulting in risks of concern for re-entry workers.

For the registered uses on mushrooms and celery seedbeds, cancer risk estimates were below 1×10^{-5}, and were not of concern, when assuming the maximum application rate per production cycle. For greenhouse ornamentals, exposure to workers cutting treated roses was assessed. This exposure scenario is expected to result in the highest exposure for re-entry worker and, therefore, conservative to all exposure scenarios. Non-cancer and cancer risk estimates were not of concern for up to four applications per floral production cycle. On this basis, the PMRA is proposing that the label of products containing chlorothalonil registered for use on greenhouse ornamentals be amended to limit its use to four applications per floral production cycle (for cut flowers) or crop production cycle (potted ornamentals and conifers) (see Appendix X and XI).

Because chlorothalonil was found to be a severe eye irritant, a 48-hour restricted-entry interval is proposed on all Canadian commercial labels for agricultural uses, greenhouses, mushroom houses, ornamentals and conifers. This requirement is consistent with the labels of some of the currently registered chlorothalonil commercial products. However, if required, individuals may be allowed to re-enter treated areas within 48 hours for short-term tasks not involving hand labour, only if at least 4 hours have passed since application, and long pants, a long-sleeved shirt, a hat, protective eyewear and chemical-resistant gloves are worn. For turf uses, including golf greens, tees and fairways, a statement is proposed on labels to prohibit entry into the treated area until sprays have dried. Finally, chlorothalonil is not currently registered for use in greenhouses on agricultural (food) crops other than celery seedbeds. A label statement prohibiting the use of products containing chlorothalonil on greenhouse-grow crops, unless clearly specified on the label (for example, celery seedbeds), is proposed. The proposed label amendments are listed in Appendix X.

3.2 Non-Occupational Exposure and Risk Assessment

3.2.1 Residential Exposure

Residential exposure is estimated using the margin of exposure approach described in Section 3.1. In the case where evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor (Q_1*) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk below 1 in 10^{-6} usually does not indicate an unacceptable risk for the general population when exposure occurs.

Homeowners can be exposed to chlorothalonil when applying treated paint and when re-entering a treated site (for example, golf courses). Toddlers can be exposed from the ingestion of paint chips.

Inhalation and incidental oral exposures from the use of treated paint were assessed by the USEPA in their 2008 Human-Health Risk Assessment. Inhalation postapplication exposure for golf courses was not assessed since inhalation exposures were determined to be negligible in outdoor postapplication scenarios. Dermal exposure was not assessed since no systemic hazard via the dermal route was identified. Cancer risks from chlorothalonil were not assessed because the USEPA determined that long-term residential exposures to chlorothalonil were not expected. In the 1999 RED, the USEPA reported Q_1* carcinogenic risk estimates ranging from 1.4×10^{-7} to 3.1×10^{-7} for homeowners applying treated paint, which was not of concern.

Non-cancer inhalation exposure and risk to adults from paint brush and airless sprayer application of treated paint (interior latex, exterior latex and exterior alkyd) was assessed. Handler exposure analyses were performed using PHED, based on an application rate of up to 5.8 g a.i./L for latex paints and up to 13 g a.i./L for outdoor use of alkyd paint. Results indicated that adult handler short- and intermediate-term inhalation exposure was not of concern.

Incidental ingestion of a paint chip by a child was assessed using the USEPA residential standard operating procedure 2.3.1, *Postapplication Potential Among Toddlers from Ingestion of Pesticide Granules from Treated Areas*. Risk was assessed assuming that the percent chlorothalonil in paint was 0.48%. The short-term margin of exposure was above the target margin of exposure (MOE) of 100, therefore, not of concern.

In addition, Environment Canada monitors air concentrations of various pesticides, including chlorothalonil, across the country, and the PMRA evaluates this data as it becomes available to ensure health risks to Canadians remain acceptable. Canadian air monitoring data, from Environment Canada and other sources, available in the published literature were considered by the PMRA to assess short- and intermediate-term inhalation bystander exposure (see Appendix VII). Maximum air concentrations were used for the short- and intermediate-term risk assessments to calculate worst case scenarios. Based on the maximum air concentration of chlorothalonil (636 ng/m^3) detected in Kensington, Prince Edward Island, inhalation risk to bystanders is not of concern, with non-cancer margins of exposure ranging from 33 708 to 220 588 (target MOE of 100) and a lifetime cancer risk estimate of 7×10^{-8} that is below the PMRA level of concern of 1×10^{-6}.

No residential uses are registered in Canada, and Canadian labels registered for use on turf contain the following statement: "This product is not to be used around homes or other residential areas such as parks, school grounds, playing fields. It is not for use by homeowners or other unlicensed users." The USEPA adequately addressed potential residential exposure in Canada, thus, the conclusions are considered applicable to the Canadian situation. Furthermore, inhalation risk to bystanders was also found to be acceptable. Based on this, no further mitigation measures with respect to residential exposure are proposed.

3.2.2 Exposure From Food and Drinking Water

As part of its 2008 Human-Health Risk Assessment for Chlorothalonil, the USEPA conducted a dietary exposure and risk assessment. An acute dietary risk assessment was not conducted because no toxic effects attributable to a single exposure to chlorothalonil were identified. A separate cancer risk assessment for chlorothalonil was also not conducted since the USEPA determined that a non-linear (margin of exposure) approach to cancer risk assessment was appropriate and the chronic reference dose was considered to be protective for that effect. In the 1999 RED, the USEPA reported an upper bound cancer risk estimate of 1.2×10^{-6} for the U.S. population which they considered to be negligible for excess lifetime cancer risk estimate.

A conservative chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID) model, resulting in exposures of 43% and 94% of the chronic reference dose for the general population of the United States and children (the most sensitive subpopulation), respectively. This assessment was based on 100% crop treated, residues at the tolerance levels, and default processing factors with the exception of tomatoes, peppers, and snap beans. The assessment also included water residues based on the highest estimated drinking water concentration (EDWC) in surface water, generated by the Pesticide Root Zone Model-Exposure Analysis Modeling System (PRZM-EXAMS)

model for a Florida horseradish application scenario (8 applications at 2.5 kg a.i./ha). The EDWC value represented both parent chlorothalonil and the degradation product of toxicological concern, 4-hydroxy-2,5,6-trichloro-1,3-dicyanobenzene. Groundwater values were not considered since they were minimal in comparison to surface water values.

The current Canadian registered uses are encompassed by the USEPA dietary risk assessment, with the exception of evening primrose, strawberries, dry peas and wheat. Despite the difference in use pattern between the United States and Canada, the dietary risk assessment conducted by the USEPA in 2008 is based on conservative assumptions (for example, 100% crops treated, residues at tolerance levels, etc.) and is expected to encompass dietary exposure to chlorothalonil in Canada.

Refined acute, chronic (non-cancer) and cancer refined dietary risk assessments were conducted by the PMRA which included all commodities currently registered for chlorothalonil in Canada and American imported commodities. These refined assessments took into account both food and water. Acute dietary exposure was estimated to 12.11% of the acute reference dose for the total population and 27.34% for children aged 1 to 2 years (the most exposed subgroup). Chronic (non-cancer) exposure was estimated to 31.6% and 69.9% of the acceptable daily intake for the general population and for children aged 1 to 2 years, respectively. Cancer risk estimates of 7.52×10^{-7} for the total population and 1.57×10^{-6} for the most exposed subgroup of infants less than 1 year old were generated, and were not of concern.

The PMRA reviewed existing Canadian water monitoring data on file (see Table 4, Appendix IX). Overall, available Canadian water monitoring concentrations were below the chlorothalonil concentrations monitored in the United States, with one exception. A concentration of chlorothalonil of 39.78 ppb was detected in ambient water that may serve as a drinking water source in New Brunswick. This value is not encompassed by the monitoring data reported in the USEPA 2008 Drinking Water Assessment. However, an acute dietary risk assessment, where a peak concentration would be used, was not required by the USEPA because no toxic effects attributable to a single exposure to chlorothalonil were identified. Furthermore, this value is encompassed by the modelled surface water yearly mean value of 68.2 ppb that was used by the USEPA in their 2008 chronic dietary risk assessment

Based on the above, dietary exposure from chlorothalonil is not of concern in Canada. No additional mitigation measure is proposed with respect to dietary exposure.

3.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to chlorothalonil. Short- and intermediate-term aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation).

Since incidental oral exposure from paint chips was considered to be episodic by the USEPA in their 2008 Human-Health Risk Assessment, only exposures for homeowners applying chlorothalonil-containing paint were included in the short- and intermediate-term aggregate non-cancer risk assessment. The scenario with the highest exposure for mixing/loading/applying paint was combined with the subpopulation with the greatest dietary exposure of those persons applying paint (namely, adults 50 years old or older) resulting in a margin of exposure of 270 (target MOE of 100), which was not of concern. Based on risk assessment generated using available Canadian air monitoring data, risk from bystander exposure is expected to be low (see Section 3.2.1) and is unlikely to result in non-cancer aggregate risks of concern in Canada.

An aggregate cancer risk assessment was conducted by the PMRA by combining the highest exposure estimates generated in PMRA and USEPA assessments for exposure to chlorothalonil from mixing/loading/applying paint with the greatest dietary exposure of those persons applying paint (namely, adults 50 years old or older) and the bystander inhalation exposure estimate for adults. An aggregate cancer risk estimate of 1×10^{-6} was generated for chlorothalonil, which is not of concern.

Overall, the Canadian aggregate exposure scenarios were adequately addressed by the USEPA aggregate non-cancer risk assessment. Based on the USEPA assessments and the aggregate cancer risk assessment conducted by the PMRA, aggregate exposure to chlorothalonil in Canada is not of concern. No additional mitigation measure is proposed with respect to aggregate exposure.

3.4 Cumulative Effects

The USEPA has not determined whether chlorothalonil has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, in their 2008 Human-Health Risk Assessment it was assumed that chlorothalonil does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.5 Incidence Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

Available information from the PMRA database, as of 19 September 2010, indicates that five incident reports related to human health or domestic animals have been submitted to the PMRA for chlorothalonil. The first incident, classified as "moderate", occurred in Canada and involved the exposure of a dog to chlorothalonil from trees sprayed in the general area of the reporter's residence. The dog exhibited vomiting, diarrhea and dehydration about 24 to 48 hours after the spraying occurred, but fully recovered after a visit to a veterinarian. A second incident, classified as "minor", involved a male applicator from Canada who was using a chlorothalonil product when the mist blew in his face and caused numbness of his lips.

The other three incidents occurred in the United States. Two of those incidents involved the use of several pesticides, including chlorothalonil. Based on this, the causality of these incidents could not be established by the PMRA. The third incident involved the use of a product containing chlorothalonil formulated as a dust. No chlorothalonil end-use products formulated as a dust are currently registered in Canada.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Terrestrial Environment
Chlorothalonil would be considered to be slightly volatile from moist soil. Hydrolysis is not expected to be an important route of transformation for chlorothalonil in the environment at relevant pH's, although hydrolysis is expected to occur in moist alkaline soils. Chlorothalonil and the major transformation product SDS-3701 are stable to phototransformation on silt loam and silty clay loam soil. Phototransformation is not expected to be an important route of transformation on soil surfaces in the field for chlorothalonil or the major transformation product SDS-3701.

Chlorothalonil is expected to transform microbially in aerobic soils at rates dependent primarily on the type of soil. The DT_{50}s of chlorothalonil in various soils range from 3 to 37 days. Based on these results, chlorothalonil is expected to be non-persistent to slightly persistent in soil. Chlorothalonil was shown to transform to two major nonpolar transformation products (SDS-3701 and SDS-19221) and to three minor polar, water-soluble transformation products (SDS-46851, SDS-47525, SDS-4724/3). SDS-3701 produced from parent chlorothalonil biotransforms slowly in aerobic soil. SDS-3701 is expected to persist and carryover in soils where chlorothalonil has been applied.

Chlorothalonil is expected to be non-persistent in flooded or poorly drained soils. Anaerobic half-lives of chlorothalonil (combined water and soil) in two different flooded soils (silt loam and sandy loam) were in the range of 5 to 15 days. Chlorothalonil binds rapidly to flooded silty loam and sandy loam soils in hydrosoil mixtures under anaerobic conditions. The same five transformation products produced in aerobic soils (for example, SDS-3701, SDS-47524, SDS-19221, SDS-47525 and SDS-46851) are also produced in anaerobic soils. SDS-3701 is the only major transformation product (for example, up to 43% of parent) formed under anaerobic conditions in soil.

Chlorothalonil is immobile in sandy loam, silty loam and clay loam soils and exhibits a low potential to leach through sandy soil. The groundwater ubiquity score classifies chlorothalonil as a non-leacher and chlorothalonil only satisfies half of the criteria set out by Cohen *et al.* (1984); PMRA No. 1918520 in some soils, both of which indicate that chlorothalonil does not have a high potential to leach. Chlorothalonil residues, however, have been detected in groundwater in some regions of Canada most notably P.E.I. (Appendix IX, Table 4), which may be explained by high use on sandy soils, preferential flow and shallow water tables. The major soil

transformation product, SDS-3701, exhibits a potential to leach through sandy loam and silty loam soils, a low potential to leach through clay loam soil and a high potential to leach through sandy soil.

The half-life of chlorothalonil in Ontario muck and sandy loam soil was 12 and 52 days, respectively. With these relatively short half-lives, carryover of chlorothalonil to the next field season would not be expected. The major soil transformation product of chlorothalonil, SDS-3701, was detected mainly in the top 15 cm depth of both Ontario muck and sandy loam soils, but trace amounts were observed to a depth of 30 cm in muck soil and 135 cm in sandy loam soil. Carryover of SDS-3701 to the next field season of up to 25% is expected to occur, thus resulting in the potential for it to accumulate annually in both muck and sandy loam soils.

Field dissipation data showed that chlorothalonil rapidly declined in both Saskatchewan (DT_{50} = 5 days and DT_{90} = 129 days) and Manitoba (DT_{50} = 7 days and DT_{90} = 60 days) clay loam and loam soils cropped with lentils. Chlorothalonil residues were shown to remain mainly in the upper 15 cm layer of soil at both Prairie study locations which further supports the conclusion that chlorothalonil has a low potential to leach. The SDS-3701 transformation product was also found mainly in the top 15 cm of soil and was shown to be relatively stable to further transformation over a 452 days sampling period in Saskatchewan and a 795 days sampling period in Manitoba. As a result of this long-term persistence, SDS-3701 can be expected to persist and carryover to subsequent field seasons when chlorothalonil is applied on an annual or semi-annual basis in the Prairies.

The octanol/water partition coefficient (log K_{ow}) was reported to be 2.88 which indicates that chlorothalonil has a potential for bioaccumulation in biota. In separate studies with bluegill sunfish and oysters, parent chlorothalonil did not bioconcentrate appreciably. For fish, bioconcentration factors (BCFs) are 75 fold in edible portions and 264 fold in whole fish for bluegill, 9.4 fold in edible portions and 16 fold in whole fish for catfish indicating that the bioaccumulation potential of chlorothalonil is low.

Environmental fate data in the terrestrial environment for chlorothalonil are summarized in Table 1 of Appendix VIII.

Aquatic environment

The reported solubility of chlorothalonil in water (0.81 mg/L at 25°C), would classify it as sparingly soluble. Hydrolysis is not expected to be an important route of chlorothalonil transformation in the environment at relevant pH's, although hydrolysis is expected to occur in alkaline aquatic environments. Phototransformation is not expected to be an important route of chlorothalonil transformation in aquatic environments. The transformation product SDS-3701, phototransforms relatively quickly (DT_{50} = 53 min at 18°C) to unidentified nonpolar products. Phototransformation, therefore, is expected to be an important route of SDS-3701 transformation in aquatic environments.

In aquatic environments biotransformation is expected to be an important transformation pathway. Chlorothalonil is bound and transformed rapidly in marine and fresh water/sediment, with half-lives of 20.4 and 12.8 hours, respectively, at 25°C. Chlorothalonil is transformed to two major (SDS-67042 and SDS-67042 sulfoxide) and four minor transformation products (SDS-66382, SDS-66432, SDS-13353 and SDS-3701) in marine and fresh water/sediments.

Chlorothalonil may be transported via surface water movement or accumulate in bottom sediment via sedimentation of chlorothalonil-bound material. In aquatic environments, chlorothalonil is expected to bind or adsorb strongly to suspended particulates and sediment.

Environmental fate data in the aquatic environment for chlorothalonil are summarized in Table 2 of Appendix VIII.

4.2 Effects on Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (for example, protection at the community, population or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios, for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the Level Of Concern (LOC). If the screening level risk quotient is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible. Data derived from monitoring studies may also be used in refining a risk assessment (Appendix IX).

4.2.1 Effects on Terrestrial Organisms

A risk assessment of chlorothalonil to terrestrial organisms was based upon an evaluation of toxicity data for the following (Table 3, Appendix VIII):

- one earthworm species, one bee species (acute exposure);
- three bird and one mammal species representing vertebrates (acute, dietary, reproduction exposure); and
- ten plant species.

For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with chlorothalonil. For multiple applications the cumulative application rates were calculated in soil using the most conservative soil field dissipation DT_{50} (52 days from an Ontario sandy loam soil). The cumulative EEC on foliage for multiple applications is estimated by adjusting the sum of the applications for dissipation between applications using a half-life on plants of 10 days, which is considered to be a reasonable conservative estimate of typical foliar half-lives based on a dataset from Willis and McDowell (1987): PMRA No. 2019147; in this dataset, 93% of the reported values were less than 10 days.

Terrestrial Invertebrates
The screening level risk assessment indicated that the level of concern for earthworms and bees was not exceeded for any of the application rates. Table 4 (Appendix VIII) summarizes the screening level risk to earthworms and bees from chlorothalonil.

Terrestrial Plants
The NOELs for ten species of non-target terrestrial plants for both seedling emergence and vegetative vigor were >17.9 kg a.i./ha. Since the golf course use-pattern will not result in appreciable exposure to non-target plants on the site of application and the NOEL is much higher than the application rate for any of the remaining uses, non-target terrestrial plants are expected to be at negligible risk on the sites of application following all the registered uses in Canada. Non-target plants adjacent to the site of application could also be exposed from residues in drift following applications of chlorothalonil. The cumulative application rate following all the applications to golf course fairways is 15.2 kg a.i./ha (the highest cumulative application rate of all the Canadian use-patterns). Since empirical drift data indicate that when using groundboom equipment only 6% of the application rate (0.9 kg a.i./ha) will drift to areas adjacent to the site of application, non-target plants inhabiting these locations will be at negligible risk. Similarly, non-target plants in areas adjacent to the sites of application for all the other Canadian use-patterns will be at negligible risk because the application rates are much lower than the NOEL for non-target terrestrial plants (17.9 kg a.i./ha).

Birds and Small Wild Mammals

Standard exposure scenarios on vegetation and other food sources based on correlations in Hoerger and Kenaga (1972); PMRA No. 1918526 and Kenaga (1973); PMRA No.1918527 and modified according to Fletcher *et al.* (1994); PMRA No. 1918522 were used to determine the concentration of pesticide (dry weight) on various food items in the diet of birds and small wild mammals, or estimated daily exposure (EDE). Exposure is dependent on the body weight of the organism and the amount and type of food consumed. In the screening level assessment a set of generic body weights was used for birds (20, 100, 1000 g) and small wild mammals (15, 35, 1000 g) to represent a range of bird and small wild mammal species. For each body weight, the food ingestion rate (FIR; equivalent to food consumption) was based on equations from Nagy (1987); PMRA No. 1918529. It is noted that diets of animals can be highly variable from season to season as well as day to day. Furthermore, animals are often opportunists and if they encounter an abundant and/or desirable food source, they may consume large quantities of that food. For these reasons, the screening level assessment used relevant food categories for each size group consisting of 100% of a particular dietary item. These items included the most conservative residue values for plants, grains/seeds, insects and fruits. A 100% diet of plants for the smallest sizes of birds and mammals was not included as this was considered unrealistic. No small birds or mammals in North America are known to eat a diet primarily of leafy plant material or grass; a small bird or mammal would need to consume unrealistically high amounts of leafy plant material or grass to meet its energy requirements.

The exposure in the diet of birds or mammals is calculated based on the following equation.

Estimated daily exposure (EDE):

EDE (mg a.i./kg bw/day) = (FIR/bw) * EEC

where

FIR = Food ingestion rate of indicator species in dry weight (kg dry weight per day)
bw = Body Weight (kg)
EEC = Concentration of compound in dry diet (mg a.i./kg dry weight diet)

In addition, the concentration of chlorothalonil in food items contaminated from spray drift off the area being treated was also calculated taking into consideration the spray drift deposition of spray quality of ASAE medium for ground boom (6%) and airblast early season (74%) and aerial (23%) at 1 m downwind from the site of application. This would allow a determination of risk to birds and small wild mammals feeding on contaminated food items in areas immediately adjacent to the site of application.

Birds

The on-field assessment assumes that birds are being exposed to residues on food items at levels equivalent to those present immediately after application, that these levels remain constant over time and that birds would feed exclusively on a single food item (for example, small insects) within the treated area. In cases where risk quotients exceed the LOC, an additional analysis was conducted to determine the amount of contaminated food, expressed as a percentage of the daily diet that must be consumed in order to reach the LOC (calculated as 1/RQ×100).

Given the conservative nature of this assessment, an acute, dietary or chronic risk to most birds both on-field and off-field is unlikely because the LOC's were only slightly exceeded and birds would need to consume an unrealistically large proportion of a single contaminated food item over an extended time period (usually > 30% of their diet). The exception is acute dietary and chronic risk to 1000 g herbivores feeding on golf course fairways and acute dietary and chronic risk to insectivores feeding in blueberries. The on-field and off-field risk assessment for these use-patterns, body weights and feeding guilds of birds is presented in Tables 5 and 6 (Appendix VIII).

There are, however, many uncertainties that prevent a clear-cut decision regarding the possible dietary and chronic risk to large herbivores feeding on golf courses and insectivores feeding in blueberries. The actual dietary toxicity value (Table 3, Appendix VIII) was greater than the highest concentration tested (suggesting that adverse effects from the use of chlorothalonil may in fact be minimal on a dietary basis. The chronic reproductive toxicity endpoint is a no effect concentration (21 week NOEC of 1000 mg a.i./kg diet for the bobwhite quail *Colinus virginianus)*. The LOEC was 5000 mg a.i./kg diet at which overt signs of toxicity and reduced reproduction were observed. The LOEC (at which effects actually occurred) is five times greater than the NOEC value which was used for the risk assessment. The NOEC is therefore a very conservative value and reproductive effects from the use of chlorothalonil may be of minimal concern. If the LOEC is used instead of the NOEC, the daily dose increases by a factor of five to 530.9 mg a.i./kg bw/day. The chronic risk quotients for large herbivores feeding on short grass on golf courses are reduced from 5.9 to 1.2 using maximum nomogram residues and from 2.1 to 0.4 using mean nomogram residues, so the LOC is barely exceeded using maximum nomogram residues and is not exceeded using mean nomogram residues which indicates that the risk is questionable.

Small wild mammals

Similar to the bird risk assessment, given the conservative nature of this assessment, an acute or chronic risk to most small wild mammals both on-field and off-field is unlikely because the LOC's were either not exceeded or only slightly exceeded for many of the body weights and feeding guilds of small wild mammals. Additionally, they would need to consume an unrealistically large proportion of a single contaminated food item over an extended time period (usually > 30% of their diet) to reach the LOC. The exception is chronic risk to medium (0.035 kg) and large (1 kg) sized herbivores feeding on golf course fairways and on leafy foliage in blueberries. The on-field and off-field risk assessment for these use-patterns, body weights and feeding guilds of mammals is presented in Tables 5 and 6 (Appendix VIII).

There are, however, uncertainties regarding the chronic risk to small wild mammals feeding on golf course fairways and on blueberries. The chronic reproductive toxicity endpoint is a no effect concentration (two generation NOEL of 200.8 mg a.i./kg bw/day for the rat *Rattus norvegicus).* The LOEL was 1029 mg a.i./kg bw/day where increased resorptions of fetuses were observed. The LOEL (at which effects actually occurred) is five times greater than the NOEL value which was used for the risk assessment. The NOEL is therefore, a very conservative value and reproductive effects from the use of chlorothalonil may in fact, be of minimal concern. If the LOEC is used instead of the NOEC, the chronic risk quotients for medium sized herbivores feeding on short grass on golf courses are reduced from 6.9 to 1.4 using maximum nomogram residues and from 2.4 to 0.5 using mean nomogram residues. The chronic risk quotients for medium sized herbivores feeding on leafy foliage on blueberries are reduced from 6.1 to 1.2 using maximum nomogram residues and from 2.0 to 0.5 using mean nomogram residues. The LOC is, therefore, barely exceeded using maximum nomogram residues and is not exceeded using mean nomogram residues which indicates that the risk is questionable.

Risk to Birds and Small Wild Mammals – SDS-3701

The major transformation product SDS-3701 is more toxic to birds and mammals than parent chlorothalonil (Table 3, Appendix VIII). Because SDS-3701 is more toxic than parent chlorothalonil, it is important to discuss its potential for risk. In one study, residues of SDS-3701 were measured in turf clippings each day for 14 days while chlorothalonil was being applied to turf on golf greens. The highest application rate used (11.9 kg a.i./ha) was comparable to the highest application rate used in Canada on golf course fairways (12.66 kg a.i./ha) which was the highest application rate scenario used for the Canadian risk assessment. Residues never exceeded 7 mg a.i./kg wet weight (23.1 mg a.i./kg dry weight) in turf clippings (EPA RED 1999). This data was used to conduct a very conservative risk assessment on birds and small wild mammals. This residue level was then converted to an EDE using the methodology described above and compared to the acute oral, acute dietary, and chronic toxicity endpoints for birds and small wild mammals expressed as a daily dose. The resulting risk from the consumption of short grass contaminated with residues of SDS-3701 following the application of chlorothalonil to golf course fairways is summarized in Table 7 (Appendix VIII).

The acute oral, acute dietary and chronic LOC's are not exceeded for birds (1000 gram herbivores). The chronic LOC was exceeded by a factor of 5.9 for 35 gram mammals and by a factor of 3.2 for 1000 gram mammals. There are, however, some uncertainties regarding the chronic risk to small wild mammals. The most sensitive chronic toxicity value for the major transformation product SDS-3701 was the three generation NOEL of 0.5 mg a.i./kg bw/day for the rat (*Rattus norvegicus*). The LOEL was reported as 3.0 mg a.i./kg bw/day based on decreased pup weights and survival, and decreased parental bodyweights. The LOEL (at which effects actually occurred) is six times greater than the NOEL value which was used for the risk assessment. The NOEL is therefore a very conservative value and reproductive effects from the use of chlorothalonil may in fact, be of minimal concern. If the LOEL value is used in the risk assessment instead of the NOEL the chronic risk quotients are reduced from 5.9 to 0.99 for 35 gram mammals and from 3.2 to 0.53 for 1000 gram mammals, therefore, the LOC is not exceeded for either of these generic body weights (Table 7, Appendix VIII).

4.2.2 Effects on Aquatic Organisms

A risk assessment of chlorothalonil to aquatic organisms was based upon an evaluation of toxicity data for the following (Table 3, Appendix VIII):

- Eighteen freshwater invertebrate species (acute and chronic exposure);
- Eight freshwater fish species (acute and chronic exposure);
- Four freshwater algae;
- Three estuarine/marine invertebrate species (acute and chronic exposure); and
- Three estuarine/marine fish species (acute exposure).

Screening Level Assessment
The initial aquatic assessment conducted is a deterministic screening level risk assessment. This approach is conservative, and primarily designed to identify the taxonomic groups which are not at risk and/or the use scenarios which do not pose an unacceptable risk. The initial conservative screening level EEC calculations for aquatic systems were based on a direct application to water depths of 15 and 80 cm. The 15 cm depth was chosen to represent a temporary body of water that could be inhabited by amphibians, whereas, the 80 cm depth was chosen to represent a typical permanent water body for agricultural scenarios.

Multiple acute toxicity endpoints were available for freshwater invertebrates and freshwater fish (Table 3, Appendix VIII). The program ETX 2.0 was used to generate species sensitivity distributions (SSDs) for freshwater invertebrates and freshwater fish based on normally distributed toxicity data. The hazardous concentration to 5% of the species (HC_5) was then calculated for both freshwater invertebrates and freshwater fish from their respective SSD's. The HC_5 values were used to calculate the risk quotients for these groups of taxa instead of the most sensitive species tested. This provides a more scientific endpoint, which uses all of the data.

Appendix VIII, Table 8 summarizes the screening level risk assessment of chlorothalonil to aquatic organisms. The level of concern (LOC) is exceeded for all freshwater and estuarine/marine taxa so a refined aquatic risk assessment was conducted on all taxa.

Spray Drift Refinement
Similar to the terrestrial risk assessment, the risk to aquatic organisms from spray drift off the treated site was also assessed taking into consideration the spray drift deposition from spray quality of ASAE medium for ground boom (6%), airblast early season (74%) and aerial (23%) at 1 m downwind from the site of application. Appendix VIII, Table 9 summarizes the refined drift risk assessment of chlorothalonil to aquatic organisms.

The LOC is exceeded for most of the freshwater and estuarine/marine taxa for all of the use-patterns and application methods. The exceptions are the acute and chronic LOC's for freshwater invertebrates and the acute LOC for freshwater fish for groundboom applications on potatoes (Appendix VIII, Table 9). Appendix XII provides input to buffer zone models. Therefore, buffer zones will be required to mitigate the risk to aquatic organisms.

Run-off Refinement

For the Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of chlorothalonil from run-off into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide run-off from a treated field into an adjacent water body and the fate of the pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m. The EEC's from Tables 2 and 3 in Appendix IX were used for this refined assessment.

The results of the assessment are summarized in Appendix VIII, Table 10. The highest and lowest peak and 21-day values were used for the acute and chronic risk assessments, respectively, for all the application scenarios. This approach brackets the acute and chronic risk for the various exposure scenarios across the country. The lowest EEC's are observed in the Okanagan valley B.C. because this is an arid region receiving very little rainfall and hence very little run-off. The acute and chronic LOC's are exceeded for many of the freshwater taxa (particularly fish and amphibians) using the highest peak EEC's for all of the use-patterns and many of the scenarios. The acute and chronic LOC's for estuarine/marine invertebrates and the acute LOC for estuarine/marine fish are exceeded for all the use-patterns and scenarios (lower B.C. and Atlantic region) where marine exposure could occur. Aquatic organisms, therefore, may be at risk from chlorothalonil residues in run-off following applications for the different use-patterns across the country.

Risk to aquatic organisms from concentrations of chlorothalonil observed in surface water from Canadian monitoring data

A risk assessment was conducted on aquatic organisms using concentrations of chlorothalonil in surface water estimated from available Canadian monitoring data. The acute risk assessment used the 95th percentile of the maximum detected concentrations from surface water monitoring studies and the chronic risk assessment used the 95th percentile of the mean concentration for each study site including ½ the LOD for non-detects. The results of the risk assessment are presented in Appendix VIII, Table 11.

The acute LOC is exceeded for both freshwater and estuarine/marine invertebrates and fish, and for amphibians. The chronic LOC is only exceeded for freshwater algae. The highest acute exceedences are for freshwater and estuarine/marine fish and for amphibians, indicating that these organisms may be at risk from concentrations of chlorothalonil in surface waters in Canada. The monitoring data was restricted to freshwater waterbodies so it is assumed that estuarine/marine surface waters would have similar concentrations of chlorothalonil, however, this is an uncertainty. Since no chronic toxicity data were available for amphibians, the toxicity values for freshwater fish were used as surrogates, which is also an uncertainty in the risk assessment.

A second risk assessment was conducted on freshwater fish using absolute maximum concentrations of chlorothalonil observed in surface water from available Canadian monitoring data. The HC_5 from a species sensitivity distribution (SSD) using acute toxicity endpoints for fish was used as the toxicity endpoint for the risk assessment. The assessment was restricted to risk from acute exposure based on the results of the previous risk assessment. Appendix VIII, Table 12 summarizes the sites in Canada were the acute LOC for freshwater fish is exceeded. The exceedences all occurred in the Atlantic Provinces from 2006 to 2008. Sampling occurred at these sites during run-off/precipitation events, capturing peak concentrations of chlorothalonil at those locations.

However, there is some uncertainty regarding this analysis. The duration of exposure to these concentrations is unknown, whereas, the fish species used to generate the toxicity endpoint used in the analysis (HC_5 from a SSD) were exposed for a 96 hours. period. If the actual exposure period at the monitoring sites was less than 96 hr., which is quite possible, then the calculated risk may be overestimated. This analysis supports the previous spray drift and run-off refined risk assessments for freshwater fish by showing that these actual concentrations observed in Canadian surface waters from monitoring data could present a risk to freshwater fish in some regions. Incident reports from New Brunswick and P.E.I. (section 4.2.3) of fish kills which may have resulted from the run-off of chlorothalonil residues also support this risk assessment.

4.2.3 Incidence Reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the US EPA Ecological Incident Information System.

Canada
In 1994, at the Maine/New Brunswick border, 10,000 brook trout which had recently been released from a hatchery were found dead in Ouelette pond, Grand Falls, New Brunswick. Potatoes are grown in the area and it had recently rained. Maneb, esfenvalerate, and chlorothalonil were found in fish tissues but not in three water samples or one brook bank soil sample. The cause was considered "undeterminable" but "not likely due solely to pesticide run-off.".

In 1996, a fish kill was reported to the PMRA. On Prince Edward Island, 40,000 salmon (parr stage) and a large (unspecified) number of trout in and upstream of Profit's Pond were killed. Dead trout were found at least 800 meters above the pond. Dead slugs were observed up to 400 meters above the pond. Live invertebrates were observed on rocks throughout. The kill was noticed around midday on July 20, 1996. Approximately 1.25 inches of rain which had fallen in a downpour in the area of Profit's Pond on the night of July 19-20 caused considerable erosion and run-off. Similar erosive rainfall events occur in the area, but usually without noticeable effects on fish. Water and sediment analysis for 10 pesticides used in this major potato growing area detected only chlorothalonil. However, it is possible that other pesticides were present at concentrations which would cause toxic effects, but which were below the detection limit, or which may have had additive or synergistic effects. Fish tissues were not analyzed for chlorothalonil, and there was no testing for its transformation products. Conditions for late potato blight were bad at the time, and farmers were typically moving towards increased use of chlorothalonil. The closest field was about 500 meters away, while the farthest was about 2500 meters away. A water sample taken from the pond in the afternoon of July 20 contained 4 µg/L of chlorothalonil. Sediment samples taken from the pond and surrounding sites had chlorothalonil concentrations ranging from approximately 10 to 60 µg/L. An autopsy on trout indicated that they were otherwise healthy and their condition was consistent with a toxic chemical effect. Although for technical reasons Canadian authorities did not establish a definitive, formal attribution for the cause of the kill, the event does clearly show that chlorothalonil is susceptible to run-off and may cause adverse effects.

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. In 2010, an incident involving a fire in a warehouse facility in Canada where several pesticides, including products containing chlorothalonil, where being stored was reported to the PMRA. Water from fighting the fire entered a stream via the storm drain system, and a fish kill was reported. The incident was classified as "major".

United States

In 1976, after improper rinsing of equipment into a small lake in Texas, 200 to 300 fish were reportedly killed. Chlorothalonil residues of 0.275 mg/L in water and 0.250 (presumably ppm) in a fish sample were cited.

In 1984, fish were killed in Viburnum, Montana, following golf course application of several chemicals, including chlorothalonil. The specific agent of cause was undetermined, but was thought to be fungicides and herbicides sprayed on golf greens.

5.0 Pest Control Product Policy Considerations

5.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, for example, persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, chlorothalonil and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[3] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

> Chlorothalonil does not meet all Track 1 criteria and is not considered a Track 1 substance. See Appendix VIII Table 13 for comparison with Track 1 criteria.
>
> Chlorothalonil does not form any transformation products that meet all Track 1 criteria.

The technical grade active ingredients of chlorothalonil have been shown to be contaminated with chlorinated benzenes, decachlorobiphenyl and chlorinated dioxins and furans, which have been identified in the federal government's Toxic Substances Management Policy (TSMP, 1995) as Track 1 substances. The PMRA is continuing its efforts to implement the Agency's strategy to manage Track 1 contaminants in pest control products (DIR99-03). In August 2006, the technical registrants of chlorothalonil were asked to submit data from the analysis of recent production batches of this technical grade active ingredient using sensitive and readily available analytical methods. This information was used by the PMRA to evaluate the progress made towards the virtual elimination of chlorinated benzenes from chlorothalonil and whether any additional measures are warranted. The current technical registrants of chlorothalonil agricultural products report hexachlorobenzene (HCB) concentrations in their current technical products are 6.0 – 8.7 ppm, this is a 4-fold reduction from the 40 ppm previously reported (2002). HCB levels in the chlorothalonil technical for use only in paint preservative products are currently reported at 30 ppm which is lower than the previously reported levels of 218 to 240 ppm (1998 and 2000).

The reduction in HCB in the technical active ingredients has resulted in a decrease in the release of this contaminant into the environment which is consistent with the TSMP goal of virtual elimination.

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[3] DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

Other Track 1 contaminants in chlorothalonil include dioxins/furans (agricultural TGAIs: $\leq$ 0.16 ppb; paint TGAI: 0.11 ppb) and decachlorobiphenyl (DCB, PCB-209) (<0.5-15 ppm). Pentachlorobenzene (QCB) and tetrachlorobenzene (TCB) are expected to be present at levels below those for HCB. Currently, agricultural pesticides are considered to be a minor source of these Track 1 contaminants in the Canadian environment and therefore have not been targeted in the implementation of TSMP.

To ensure that PMRA has current information on Track 1 contaminants in pesticide products, new batch analyses are required for Track 1 contaminants with data >10 years old (QCB, TCB and dioxins/furans).

5.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical are compared against the list in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01[4] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[5], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Track 1 TSMP contaminants were addressed under section 5.1.

The use of formulants in registered pest control products identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6] is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[7].

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4 NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

5 DIR2006-02, PMRA Formulants Policy.

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 DIR2006-02, PMRA Formulants Policy.

6.0 Summary

6.1 Human Health Risk

Exposure to chlorothalonil may occur through consumption of food and water, and through residential exposure (for example, golf courses, treated paint). Workers can be exposed to chlorothalonil while working as a mixer, loader or applicator of products containing chlorothalonil, or by entering treated sites, such as greenhouses or agricultural fields.

Cancer and non-cancer risk estimates associated with mixing, loading and applying products containing chlorothalonil are not of concern provided the personal protective equipment outlined in Section 3.1.1 is added to product labels. Postapplication cancer and non-cancer risk to workers are not of concern provided the mitigation measures outlined in Section 3.1.2 are added to product labels. A 48-hour restricted-entry interval (REI) is proposed for agricultural uses, and use on conifers and ornamentals. Entry after 4 hours can be allowed for short-term task only with the wearing of the appropriate personal protective equipment. A restriction to the number of applications on greenhouse ornamentals is also proposed.

Residential exposure to chlorothalonil is not of concern. Acute and chronic non-cancer and cancer risk estimates associated with exposure to chlorothalonil from food and water are not of concern. Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, as well as from all known or plausible exposure routes (oral, dermal and inhalation). Aggregate non-cancer and cancer risk estimates associated with aggregate exposure to chlorothalonil from all relevant sources are not of concern.

6.2 Environmental Risk

When applied in the Canadian environment, chlorothalonil is expected to be non-persistent in soil. Chlorothalonil is immobile in most soils and has a low potential to leach to groundwater. Chlorothalonil residues, however, have been detected in groundwater in some regions of Canada most notably P.E.I. (Appendix IX, Table 4), which may be explained by high use on sandy soils, preferential flow and shallow water tables. The major transformation product SDS-3701, however, is persistent in soil and has a potential to leach in some soils. Chlorothalonil may enter aquatic environments via spray drift and run-off. Once in the aquatic environment chlorothalonil is not persistent in surface waters and is expected to bind strongly to suspended particles and to partition into sediment. Residues of chlorothalonil have been detected in surface waters in sub-arctic and arctic lakes which show that it is subject to long range transport to remote regions.

The use of chlorothalonil is not expected to present a risk to terrestrial organisms including earthworms, bees, non-target plants, birds and small wild mammals. The major transformation product SDS-3701 is more toxic than chlorothalonil to birds and mammals, however, it is also not expected to present a risk to these organisms following applications of chlorothalonil in Canada.

In the aquatic environment, run-off and drift may pose risks to freshwater and marine organisms. Several fish kill incidents associated with run-off of chlorothalonil residues have been reported in Canada and the United States. The observance of spray buffer zones can effectively mitigate the entry of spray drift into aquatic systems. Spray buffer zones will not mitigate run-off. To reduce the potential for run-off of chlorothalonil to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to run-off and when heavy rain is forecasted are required. In addition, a vegetative strip between the area and the edge of a water body is recommended to reduce run-off of chlorothalonil to aquatic areas. Environmental mitigation statements are listed in Appendix X.

7.0 Organization for Economic Co-operation and Development Status of Chlorothalonil

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 34 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the current available information on the status of chlorothalonil in other OECD member countries, chlorothalonil was assessed by the European Community rapporteur Member State, the Netherlands. The review was finalised on 15 February 2005, and chlorothalonil (fungicide uses) was found to be appropriate to be included in Annex I to Directive 91/414/EEC, and therefore may be authorized in all Member States. Particular attention must be given to the protection of aquatic organisms and the protection of groundwater when chlorothalonil is applied in regions with vulnerable soil and/or climate conditions.

Chlorothalonil is currently registered for use on fruits and vegetables, turf, ornamentals, freshly cut timber, as well as in paint in Australia. As described earlier in this document, the United States assessed the registration of all uses of chlorothalonil in 1999, and further risk assessments were conducted in 2008. The USEPA concluded that using chlorothalonil as a pesticide does not result in unreasonable adverse effects to human health or the environment provided risk-reduction measures were implemented.

As described earlier, the human health portion of the Canadian re-evaluation of chlorothalonil is largely based on the 1999 and 2008 USEPA assessments and includes additional assessments. The environmental portion of the Canadian re-evaluation of chlorothalonil is based on PMRA assessments. Mitigation measures are required to further protect human health and the environment. Overall, the status of chlorothalonil in other OECD countries has been taken into consideration in the re-evaluation of chlorothalonil in Canada.

8.0 Proposed Re-evaluation Decision

The PMRA has determined that chlorothalonil is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be revised to include the label statements listed in Appendix X. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

9.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, Pest Management Regulatory Agency Re-evaluation Program, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxiques-toxics.

The USEPA 1999 RED document for chlorothalonil, as well as the 2008 Federal Register Proposed Rule and 2009 USEPA Federal Register Final Rule, and related documents for chlorothalonil to establish specific tolerances, are available at www.regulations.gov (Docket Folder EPA-HQ-OPP-2007-1106).

Information on chlorothalonil from the European Commission can be found at Commission Directive 2005/53/EC amending Council Directive 91/414/EC to include Chlorothalonil as an active substance.

Information on the Australian Pesticides and Veterinary Medicines Authority (APVMA) Chemical Review Program can be found at http://www.apvma.gov.au/products/review/

List of Abbreviations

°C	degree(s) Celsius
µg	microgram(s)
a.i.	active ingredient
amu	atomic mass unit(s)
ASAE	American Society of Agricultural Engineers
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BHSE	British Health & Safety Executive
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
cPAD	chronic population adjusted dose
cRfD	chronic reference dose
d	day(s)
DACO	data code
DCB	decachlorobiphenyl
DEEM	Dietary Exposure Evaluation Model
DT_{50}	dissipation time to 50% (the time required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
dw	dry weight
EDWC	estimated drinking water concentration
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	expected environmental concentration [also estimated environmental exposure concentration]
EXAMS	Exposure Analysis Modeling System
FCID	Food Consumption Intake Database
FIR	food ingestion rate
FQPA	*Food Quality Protection Act*
FRAC	Fungicide Resistance Action Committee
g	gram(s)
h	hour(s)
ha	hectare
HC_5	hazardous concentration to 5% of the species
HCB	hexachlorobenzene
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient

L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
LOEL	lowest observed effect level
m	metre(s)
m^2	metre(s) squared
m^3	metre(s) cubed
mg	milligram(s)
mm Hg	millimetre mercury
MRL	maximum residue limit
min	minute(s)
MSHA	Mine Safety and Health Administration
ng	nanogram(s)
NIOSH	National Institute for Occupational Safety and Health
nm	nanometre
MOE	margin of exposure
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PCB	polychlorobenzene
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
PSF	Pesticide Science Fund
Q_1^*	cancer potency factor
QCB	pentachlorobenzene
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient
SF	safety factor
SSD	species sensitivity distributions
TCB	tetrachlorobenzene
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Data requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to the registrant by the PMRA.

For Registration Number 25574 and 27059
DACO2.13.4 Impurities of human health or environmental concern

The PMRA requires current information on levels of Track 1 contaminants identified in Dir99-03[8] and in the *Canada Gazette*[9] to assess the continued acceptability of pest control products and to monitor the progress in preventing or minimizing the release of Track 1 substances into the environment. Since the Minister considers these contaminants to be of health or environmental concern (*Canada Gazette*), the PMRA must also be able to make this information available to the public. The PMRA considers information ≤ 10 years old at the time of evaluation to be current.

A review of all the contaminant information on file for the technical products indicates that the PMRA has current information on levels of HCB. The information that the PMRA has on file for dioxin/furans levels is > 10 years old. The PMRA does not have information on current levels of tetrachlorobenzenes and pentachlorobenzene which are expected to be present in the TGAI. The following information is therefore required:

Recent analytical batch data, from a GLP compliant or government accredited laboratory, must be provided for the TSMP Track 1 microcontaminants pentachlorobenzene and tetrachlorobenzenes (3 isomers). The analytical method(s) used must utilize the lowest practical limits of quantitation and be fully specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.

Recent analytical batch data, from a GLP compliant or government accredited laboratory, must be provided for all identifiable dioxins and furans from at least five batches of TGAI manufactured at the registered site. This will include data for the 17 substances listed in Table 4 of the Priority Substances List 1 document "Polychlorinated dibenzodioxins and polychlorinated dibenzofurans" - http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/dioxins_furans_dioxines_furannes/index_e.html.

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8 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

9 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

The analytical method(s) used must utilize the lowest practical limits of quantitation and be fully specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.

For Registration Number 29354
DACO2.13.4 Impurities of human health or environmental concern

The PMRA requires current information on levels of Track 1 contaminants identified in Dir99-03[10] and in the *Canada Gazette*[11] to assess the continued acceptability of pest control products and to monitor the progress in preventing or minimizing the release of Track 1 substances into the environment. Since the Minister considers these contaminants to be of health or environmental concern (*Canada Gazette*), the PMRA must also be able to make this information available to the public. The PMRA considers information ≤ 10 years old at the time of evaluation to be current.

A review of all the contaminant information on file for the technical products indicates that the PMRA has current information on levels of HCB, dioxins/furans and PCBs. However, the PMRA does not have information on the levels of tetrachlorobenzenes and pentachlorobenzene which are expected to be present in the TGAI. The following information is therefore required:

> Recent analytical batch data, from a GLP compliant or government accredited laboratory, must be provided for the TSMP Track 1 microcontaminants pentachlorobenzene and tetrachlorobenzenes (3 isomers). The analytical method(s) used must utilize the lowest practical limits of quantitation and be fully specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.

For Registration Number 15724 and 28354
DACO 10.2.3.3 Small-scale Efficacy Trials

The registrant is required to confirm that the proposed new rates will provide control of specific diseases on turf grass. Data must be generated on golf course turf demonstrating the control of helminthosporium leaf spot or brown patch using the appropriate end-use product.

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[10] DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

[11] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

Appendix II Registered Products Containing Chlorothalonil as of 15 December 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
15723	Commercial	Syngenta Crop Protection Canada Inc.	Bravo 500 Agricultural Fungicide	Suspension	500 g/L
15724	Commercial	Syngenta Crop Protection Canada Inc.	Daconil 2787 Flowable Fungicide	Suspension	500 g/L
16354	Commercial	Syngenta Crop Protection Canada Inc.	Tuffcide N-96 Paint Microbiocide	Powder	96%
16354.03	Commercial	ISP Canada Corp.	Fungitrol 960	Powder	96%
18965	Commercial	Syngenta Crop Protection Canada Inc.	Tuffcide N-40-D Paint Microbiocide	Suspension	40.4%
18965.06	Commercial	ISP Canada Corp.	Fungitro 404-D	Suspension	40.4%
24544	Commercial	Bayer Cropscience Inc.	Tattoo C Suspension Concentrate Fungicide	Suspension	375 g/L
24793	Commercial	Syngenta Crop Protection Canada Inc.	Bravo Ultrex 90 SDG Agricultural Fungicide	Water dispersible granules	90%
24915	Manufacturing concentrate	Bayer Cropscience Inc.	Tattoo Manufacturing Use Product	Suspension	375 g/L
25574	Technical	GB Biosciences Corp.	Technical Chlorothalonil Fungicide	Solid	98.5%
26443	Commercial	Syngenta Crop Protection Canada Inc	Ridomil Gold Bravo Twin Pack Fungicide	Suspension	480 g/L
27057	Commercial	Sostram Corporation	Clortram P-98M	Dust	98%
27057.01	Commercial	Cognis Canada Corporation	Nopcocide N-98	Dust	98%
27057.02	Commercial	ISP Canada Corp.	Fungitrol 960S Fungicide	Dust	98%
27058	Commercial	Sostram Corporation	Clortram F-40	Suspension	40.4%
27058.01	Commercial	Cognis Canada Corporation	Nopcocide N-40-D	Suspension	40.4%
27058.02	Commercial	Buckman Laboratories of Canada Ltd.	Busan 1192D Microbiocide	Suspension	40.4%
27058.03	Commercial	ISP Canada Corp.	Fungitrol 404-DS Fungicide	Suspension	40.4%
27059	Technical	Sipcam Agro USA, Inc.	Chlorothalonil Technical Fungicide	Dust	98%
27540	Manufacturing concentrate	Syngenta Crop Protection Canada Inc	Tuffcide N-40-D Manufacturing Concentrate	Suspension	40.4%
27541	Manufacturing concentrate	Syngenta Crop Protection Canada Inc	Tuffcide N-96 Manufacturing Concentrate	Solid	96%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
28354	Commercial	Syngenta Crop Protection Canada Inc	Daconil Ultrex Fungicide	Water dispersible granules	82.5%
28861	Commercial	Syngenta Crop Protection Canada Inc	Instrata TM Fungicide	Suspension	362 g/L
28900	Commercial	Syngenta Crop Protection Canada Inc	Bravo ZN Agricultural Fungicide	Suspension	500 g/L
29225	Commercial	Syngenta Crop Protection Canada Inc	Bravo 720	Suspension	720 g/L
29237	Commercial	Syngenta Crop Protection Canada Inc	Ridomil Gold SL/Bravo720 Twin-Pak	Suspension	720 g/L
29238	Commercial	Syngenta Crop Protection Canada Inc	Ridomil Gold/Bravo 720 Twin-Pak	Emulsifiable concentrate	720 g/L
29239	Commercial	Syngenta Crop Protection Canada Inc	Ridomil Gold SL/Bravo Twin-Pak	Suspension	500 g/L
29306	Commercial	Syngenta Crop Protection Canada Inc	Bravo Ultrex	Water dispersible granules	82.5%
29354	Technical	Sipcam Agro USA Inc.	Chlorothalonil Technical AG	Powder	99.3%
29355	Commercial	Sipcam Agro USA Inc.	Echo 720 Agricultural Fungicide	Suspension	720 g/L
29356	Commercial	Sipcam Agro USA Inc.	Echo 90 DF Agricultural Fungicide	Dry Flowable	90%
29642	Commercial	Syngenta Crop Protection Canada Inc.	Concert Fungicide	Suspension	483 g /L
29647	Commercial	Rohm and Haas Canada LP	Rocima 404D Microbiocide	Suspension	40.4%

Appendix III Toxicological Endpoints Selected by the USEPA for Chlorothalonil Health Risk Assessments (2008 Assessments)

Exposure Scenario (route and period of exposure)	Dose Used in Risk Assessment	Study	UF/SF or Target MOE [a]
Chronic dietary (general population)	NOAEL = 2.0 mg/kg bw/day cRfD = cPAD = 0.02 mg/kg bw/day	Chlorothalonil chronic rat LOAEL = 4.0 mg/kg bw/day, based on epithelial cell hyperplasia, clear cell hyperplasia and karyomegaly in the kidneys of male rats.	UF = 100 [b] FQPA SF = 1
Short-term (1-30 days) Incidental Oral	NOAEL = 3.0 mg/kg bw/day	Chlorothalonil 90-day rat LOAEL = 10.0 mg/kg bw/day, based on dilated renal medullary tubules and hyperplasia and hyperkeratosis of the non-glandular area of the stomach.	MOE = 100 [c]
Short-term (1-30 days) Inhalation	NOAEL = 3.0 mg/kg bw/day (oral end-point) Inhalation absorption factor = 100%	Chlorothalonil 90-day rat LOAEL = 10.0 mg/kg bw/day, based on dilated renal medullary tubules and hyperplasia.	Residential MOE = 100 [c] Occupational MOE = 100 [b]
Intermediate-term (1-6 months) Inhalation	NOAEL = 3.0 mg/kg bw/day (oral end-point) Inhalation absorption factor = 100%	Chlorothalonil 90-day rat LOAEL = 10.0 mg/kg bw/day, based on dilated renal medullary tubules and hyperplasia.	Residential MOE = 100 [c] Occupational MOE = 100 [b]
Cancer (oral, dermal, inhalation)	Classification: "Likely to be a human carcinogen by all routes of exposure". EPA supports the MOE approach for chlorothalonil.		

[a] UF/SF refers to total of uncertainty and/or Safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments.

[b] 10 fold for intraspecies extrapolation; 10 fold for interspecies extrapolation

[c] 10 fold for intraspecies extrapolation; 10 fold for interspecies extrapolation; 1 fold for FQPA SF

cPAD = population adjusted chronic reference dose; cRfD = chronic reference dose; FQPA SF = *Food Quality Protection Act* Safety Factor; MOE = margin of exposure; NOAEL = no observed adverse effect level assessment; LOAEL = lowest observed adverse effect level; UF = uncertainty factor

Appendix IV Toxicological Endpoints Selected by the USEPA for Chlorothalonil Cancer Risk Assessments (1999 RED)

Exposure Scenario (route and period of exposure)	Dose Used in Risk Assessment	Study	LOC or Target MOE [a]
Cancer for Chlorothalonil (MOE approach) (oral, dermal, inhalation)	NOAEL = 1.5 mg/kg bw/day	Chlorothalonil cell proliferation study in rats, LOAEL = 15 mg/kg bw/day based on toxic response of the kidney and forestomach	At the time of the RED, the USEPA has not determined that chlorothalonil is a non-linear carcinogen.
Cancer for Chlorothalonil (Q_1* approach) (oral, dermal, inhalation)	Q_1* = 7.66×10^{-3} $(mg/kg\ bw/day)^{-1}$	Chronic toxicity/carcinogenicity study in rats, based on evidence of increased incidence of renal adenomas, carcinomas and adenomas/carcinomas combined in rats and mice following chronic dosing at 15 and 175 mg/kg bw/day, as well as increased incidence of forestomach carcinomas in CD/1 mice and papillomas and/or carcinomas combined in Fisher 344 rats. A ¾ scaling factor was applied to the Q_1*.	Residential LOC = risk estimate >1 × 10^{-6} Occupational LOC = risk estimate >1 × 10^{-5}

[a] LOC refers to desired cancer risk estimate and MOE refers to desired margin of exposure for occupational or residential assessments.

LOC = Level of concern; MOE = margin of exposure; NOAEL = no observed adverse effect level assessment; LOAEL = lowest observed adverse effect level

Appendix V Toxicological Endpoints Selected by the PMRA for Chlorothalonil Greenhouse and Mushroom House Risk Assessments (based on 1999 RED)

Exposure Scenario (route and period of exposure)	Dose Used in Risk Assessment	Study	LOC or Target MOE [a]
Long-term (> 6 months) Dermal	NOAEL = 2.0 mg/kg bw/day (oral end-point) Dermal absorption factor = 0.15%	Two-year rat study, LOAEL = 4.0 mg/kg bw/day, based on increased kidney weight and epithelial hyperplasia in the proximal convoluted tubules of the kidney in the males.	MOE = 100
Cancer (Q_1* approach) (oral, dermal, inhalation)	Q_1* = 7.66×10^{-3} $(mg/kg\ bw/day)^{-1}$	Chronic toxicity/carcinogenicity study in rats, based on evidence of increased incidence of renal adenomas, carcinomas, and adenomas/carcinomas combined in rats and mice following chronic dosing at 15 and 175 mg/kg bw/day, as well as increased incidence of forestomach carcinomas in CD/1 mice and papillomas and/or carcinomas combined in Fisher 344 rats. A ¾ scaling factor was applied to the Q_1*.	LOC = risk estimate $>1 \times 10^{-5}$

[a] LOC refers to desired cancer risk estimate and MOE refers to desired margin of exposure for occupational assessments. LOC = Level of concern; MOE = margin of exposure; NOAEL = no observed adverse effect level assessment; LOAEL = lowest observed adverse effect level

Appendix VI Canadian Maximum Residue Limits Established for Chlorothalonil as of 26 November 2009

Commodity	Canadian MRL[1]
Asparagus	0.1
Balsam apples, balsam pears, beans, broccolis, Brussels sprouts, cabbages, cantaloupes, cauliflowers, chayote fruits, Chinese cucumbers, Chinese waxgourds, citron melons, cucumbers, edible gourds (other than those listed in this item), muskmelons (other than those listed in this item), onions, pumpkins, summer squash, tomatoes, wasabi, watermelons, West Indian gherkins, winter squash	5
Blueberries	0.6
Carrots, mushrooms, parsnips	1
Celery	15
Cherries, peaches, nectarines	0.5
Chickpea [2]	7
Corn (sweet) [3], evening primroses	0.1
Cranberries	2
Peanuts	0.3
Potatoes [3]	0.08

[1] Canadian MRLs were established based on combined residues of chlorothalonil and its 4-hydroxy metabolite.
[2] Proposed MRL (PMRL2010-05)
[3] Proposed MRLs (PMRL2010-10)

Appendix VII Detections of Chlorothalonil in Canadian Air Monitoring Studies

Data Source	Sample Date	Location	Maximum (ng/m^3)	Mean (ng/m^3)
PMRA 1807707	1999	Summerside (farm), PEI	636	284
PMRA 1807707	1998	All farm sites	458	128
		Abram (control), PEI	3.9	2.5
		Kensington (farm), PEI	458	193
		Miscouche (farm), PEI	410	169
		Sherbrooke (farm), PEI	45	22
PMRA 1536782	2003	Abbotsford, BC	—	NA
		Egbert, ON	—	5.200
		St. Anicet, QC	—	3.030
		Baie St. Francois, QC	—	1.860
		Kensington, PEI	—	11.900
PMRA 2025689	2003	Toronto, ON (urban)	—	0.480
		Downsview, ON (urban)	—	0.460
		Egbert, ON (rural)	—	1.740
		Trent, ON (forested)	—	0.002
		Haliburton, ON (forested)	—	0.007
		Sprucedale, ON (forested)	—	0.010
		Loxton Lake, ON (forested)	—	0.001
		Fraserdale, ON (forested)	—	0.015
PMRA 2025688	2004	St. Damase, QC May to June (weekly)	4.900	2.057
		St. Damase, QC July to September (monthly)	5.074	2.899
PMRA 2025690	2006-2007	Egbert, ON (continuous monitoring)	2.845	0.918

Appendix VIII Environmental Fate and Toxicity

Table 1 Fate and Behaviour in the Terrestrial Environment

Property	Value	Transformation products	Comments
Abiotic Transformation			
Hydrolysis	Stable to hydrolysis at pH 5 and 7. Hydrolyzes (DT_{50} = 38 days) at pH 9	SDS-3701 (22%) and SDS-19221 (55%)	Not expected to be an important route of transformation in the environment at relevant pH's.
Phototransformation on soil	Stable to phototransformation on silt loam and silty clay loam soil.	Major transformation product, SDS-3701, is also stable to phototransformation on silt loam and silty clay loam soil.	Not expected to be an important route of transformation on soil surfaces in the field for either chlorothalonil or SDS-3701.
Phototransformation in air	—	—	Data are not required since chlorothalonil is not expected to be volatile under field conditions.
Biotransformation			
Biotransformation in aerobic soil	The half-lives of chlorothalonil in various soils ranges from 3 to 37 days.	Two major transformation products (SDS-3701 and SDS-19221). SDS-3701 is expected to persist and carryover in soils where chlorothalonil has been applied.	Expected to be an important route of transformation.
Biotransformation in anaerobic soil	The half-life of chlorothalonil was 5 to 15 days in silty loam and sandy loam soil, respectively.	SDS-3701 is the only major transformation product (for example, 43% of parent)	Expected to be an important route of transformation.
Mobility			
Adsorption/ desorption in soil	Freundlich Koc values for chlorothalonil range from 1,300 - 14,000	SDS-3701 has a medium mobility ranking in soil. SDS-46851 has a high mobility ranking in soil.	Mobility of chlorothalonil ranges from immobile in silt to slight mobility in silty clay loam according to the classification of McCall *et al.* (1980, PMRA No. 2024011).
Soil leaching	—	The major soil transformation product, SDS-3701, exhibits a potential to leach through sandy loam and silty loam soils, a low potential to leach through clay loam soil and a high potential to leach through sandy soil.	Chlorothalonil is immobile in sandy loam, silty loam and clay loam soils and exhibits a low potential to leach through sandy soil.

Property	Value	Transformation products	Comments
Volatilization	—	—	Chlorothalonil is not expected to volatilize under field conditions
Field studies			
Field dissipation	Half-life of chlorothalonil in Ontario muck and sandy loam soil was 12 and 52 days. The DT_{50} of chlorothalonil in northern Ohio sandy loam was 59 days. Chlorothalonil rapidly declined in both Saskatchewan (DT_{50} = 5 days and DT_{90} = 129 days) and Manitoba (DT_{50} = 7 days and DT_{90} = 60 days) clay loam and loam soils cropped with lentils.	Half-life of SDS-3701 in Ontario muck and sandy loam soil was calculated to be 23 and 5 days, respectively. SDS-3701 can be expected to persist and carryover to subsequent field seasons when chlorothalonil is applied on an annual or semi-annual basis in the Prairies.	—
Field leaching	Chlorothalonil was not generally detected below a depth of 15 cm in Ontario muck soil. Chlorothalonil was detected in sandy loam soil to a depth of 45 cm. Chlorothalonil residues were shown to remain mainly in the upper 15 cm layer of soil at both Prairie study locations, it is not expected to leach to groundwater in either the south-central or north-central Prairie regions.	SDS-3701, was detected mainly in the top 15 cm depth of both Ontario muck and sandy loam soils, but trace amounts were observed to a depth of 30 cm in muck soil and 135 cm in sandy loam soil. The other major soil transformation product of chlorothalonil, SDS-19221, was detected to a depth of 30 cm in both types of soil.	—

Table 2 Fate and Behaviour in the Aquatic Environment

Study type	Value	Transformation products	Comments
Abiotic transformation			
Hydrolysis	Stable to hydrolysis at pH 5 and 7. Hydrolyzes (DT_{50} = 38 days) at pH 9.	SDS-3701 (22%) and SDS-19221 (55%)	Not expected to be an important route of transformation in the environment at relevant pH's.
Phototransformation in water	At pH 7, chlorothalonil phototransforms slowly (DT_{50} = 776 hours, or 65 12-hours sunlight days at 25°C).	SDS-3701 (10.8-12.5%)	Phototransformation is not expected to be an important route of chlorothalonil transformation in aquatic environments. Phototransformation, is expected to be an important route of SDS-3701 transformation in aquatic environments.

Biotransformation			
Biotransformation in aerobic water systems	Chlorothalonil is bound and transformed rapidly in marine and fresh water/sediment, with half-lives of 20.4 and 12.8 hours, respectively, at 25°C.	SDS-67042 (29.2-30.9%) SDS-67042 hydroxide (12.1 - 16.5%)	Biotransformation is expected to be an important route of transformation of chlorothalonil in aquatic environments.
Biotransformation in anaerobic water systems	—	—	A valid anaerobic sediment/water biotransformation study for chlorothalonil is not available.
Partitioning			
Adsorption/ desorption in sediment	—	—	—
Field studies			
Field dissipation	—	—	A valid aquatic field dissipation study for chlorothalonil is not available.

Table 3 Environmental Toxicity of Chlorothalonil

Organism	Study Type	Species	Test material	Endpoint	Value	Toxicity Category
Terrestrial Species						
Invertebrates	Acute	Earthworm (*Eisenia foetida*)	Chlorothalonil technical	14-day LC_{50}	**515 mg a.i./kg substrate**	—
	Acute	Honey bee (*Apis mellifera*)	Chlorothalonil technical	48-h LD_{50}	**> 40 µg a.i./bee**	Relatively non-toxic
Birds	Acute oral	Mallard duck (*Anas platyrhynchos*)	96% a.i.	Single exposure LD_{50}	> 4640 mg a.i./kg bw	Practically non-toxic
		Japanese quail (*Coturnix japonica*)	98.6% a.i.	Single exposure LD_{50}	**> 2000 mg a.i./kg bw**	Practically non-toxic
		Mallard duck (*Anas platyrhynchos*)	99% SDS-3701	Single exposure LD_{50}	**158 mg a.i./kg bw**	Moderatel y toxic
	Dietary	Bobwhite quail (*Colinus virginianus*)	96% a.i.	8 day LC_{50}	**> 10,000 mg a.i./kg diet**	Practically non-toxic
		Mallard duck (*Anas platyrhynchos*)	96% a.i.	5 day LC_{50}	**> 10,000 mg a.i./kg diet**	Practically non-toxic
		Bobwhite quail (*Colinus virginianus*)	99% SDS-3701	5 day LC_{50}	**1746 mg a.i./kg diet**	Slightly toxic

Organism	Study Type	Species	Test material	Endpoint	Value	Toxicity Category
		Mallard duck (*Anas platyrhynchos*)	99% SDS-3701	5 day LC_{50}	2000 mg a.i./kg diet	Slightly toxic
	Chronic (repro)	Bobwhite quail (*Colinus virginianus*)	98.3% a.i	21 week NOEC LOEC	**1,000 mg a.i./kg diet** 5000 mg a.i./kg diet (reduced reproduction)	—
		Mallard duck (*Anas platyrhynchos*)	98.3% a.i.	18 week NOEC	> 10,000 mg a.i./kg diet	—
		Bobwhite quail (*Colinus virginianus*)	99% SDS-3701	21 week NOEC	100 mg a.i./kg diet	—
		Mallard duck (*Anas platyrhynchos*)	99% SDS-3701	19 week NOEC LOEC	**50 mg a.i./kg diet** 100 mg a.i./kg diet (reduction egg shell thickness)	—
Mammals	Acute oral	Rat (*Rattus norvegicus*)	Chlorothalonil technical	LD_{50}	**> 10,000 mg a.i./kg bw**	Practically non-toxic
		(*Rattus norvegicus*)	SDS-3701	LD_{50}	**242 mg a.i./kg bw**	Moderatel y toxic
	Chronic (repro)	Rat (*Rattus norvegicus*)	Chlorothalonil technical	2 generation NOAEL LOEL	**200.8 mg a.i./kg bw/day** 1029 mg a.i./kg bw/day (increased resorptions of fetuses)	—
		Rat (*Rattus norvegicus*)	SDS-3701	3 generation NOAEL LOAEL	**0.5 mg a.i./kg bw/day** 3.0 mg a.i./kg bw/day (decreased pup weights and survival)	—
Nontarget Plants	Seedling emergence	10 species	97.9% a.i.	NOEL	**> 17.9 kg a.i./ha**	—
	Vegetative vigor	10 species	97.9% a.i.	NOEL	**> 17.9 kg a.i./ha**	—

Organism	Study Type	Species	Test material	Endpoint	Value	Toxicity Category
Freshwater Organisms						
Invertebrates	Acute	Waterflea (*Daphnia magna*)	Chlorothalonil technical	48-h LC_{50}	68.0 µg a.i./L	Very highly toxic
		Caddisfly *Leptocerus*	Chlorothalonil technical	48-h EC_{50}	38.0 µg a.i./L	Very highly toxic
		Amphipod *Crangonyx pseudogracillis*	Chlorothalonil technical	48-h EC_{50}	64.0 µg a.i./L	Very highly toxic
		Cladoceran *Chydorus*	Chlorothalonil technical	48-h EC_{50}	74.0 µg a.i./L	Very highly toxic
		Pond snail *Lymnea stagnalis*	Chlorothalonil technical	48-h EC_{50}	260.0 µg a.i./L	Highly toxic
		Snail *Planorbis*	Chlorothalonil technical	48-h EC_{50}	120.0 µg a.i./L	Highly toxic
		Leech *Erpobdella*	Chlorothalonil technical	48-h EC_{50}	160.0 µg a.i./L	Highly toxic
		Flatworm Planaria	Chlorothalonil technical	48-h EC_{50}	200.0 µg a.i./L	Highly toxic
		Copepod *Macrocyclops fuscus*	Chlorothalonil technical	48-h EC_{50}	260.0 µg a.i./L	Highly toxic
		Amphipod *Gammarus pulex*	Chlorothalonil technical	48-h EC_{50}	240.0 µg a.i./L	Highly toxic
		Amphipod *Hyalella azteca*	Chlorothalonil technical	48-h EC_{50}	250.0 µg a.i./L	Highly toxic
		Chironomid *Chironomus riparius*	Chlorothalonil technical	48-h EC_{50}	61.0 µg a.i./L geometric mean	Very highly toxic
		Seed shrimp *Ostracoda*	Chlorothalonil technical	48-h EC_{50}	390.0 µg a.i./L	Highly toxic
		Water louse *Asellus aquaticus*	Chlorothalonil technical	48-h EC_{50}	450.0 µg a.i./L	Highly toxic
		Mayfly nymph *Cloeon dipterum*	Chlorothalonil technical	48-h EC_{50}	600.0 µg a.i./L	Highly toxic
		Damselfly *Ischnura elegans*	Chlorothalonil technical	48-h EC_{50}	560.0 µg a.i./L	Highly toxic

Organism	Study Type	Species	Test material	Endpoint	Value	Toxicity Category
		Glass shrimp *Parataya australiensis*	Chlorothalonil technical	96-h LC_{50}	16.0 µg a.i./L	Very highly toxic
		Giant freshwater crayfish *Astacopsis gouldi*	Chlorothalonil technical	96-h LC_{50}	**12.0 µg a.i./L**	Very highly toxic
		Waterflea (*Daphnia magna*)	SDS-3701	48-h EC_{50}	**26000 µg a.i./L**	Slightly toxic
	Chronic	Waterflea (*Daphnia magna*)	99.8% a.i.	21-d NOEC (survival, offspring/ female)	**39.0 µg a.i./L**	—
		Chironomid *Chironomus riparius*	Chlorothalonil technical	28-d NOEC	40.0 µg a.i./L	—
Fish	Acute	Rainbow trout *(Oncorhynchus mykiss)*	Chlorothalonil technical	96-h LC_{50}	38.0 µg a.i./L (geometric mean)	Very highly toxic
		Bluegill sunfish (*Lepomis macrochirus*)	Chlorothalonil technical	96-h LC_{50}	52.0 µg a.i./L (geometric mean)	Very highly toxic
		Fathead minnow (*Pimphales promelas*)	Chlorothalonil technical	96-h LC_{50}	23.0 µg a.i./L	Very highly toxic
		Carp (*Cyprinus carpio*)	Chlorothalonil technical	96-h LC_{50}	76.0 µg a.i./L (geometric mean)	Very highly toxic
		Channel catfish (*Ictalurus punctatus*)	Chlorothalonil technical	96-h LC_{50}	47.0 µg a.i./L	Very highly toxic
		Common jollytail (*Galaxias maculatus*)	Chlorothalonil technical	96-h LC_{50}	**16.0 µg a.i./L**	Very highly toxic
		Western trout minnow (*Galaxias truttaceus*)	Chlorothalonil technical	96-h LC_{50}	19.0 µg a.i./L	Very highly toxic
		Golden galaxias (*Galaxias auratus*)	Chlorothalonil technical	96-h LC_{50}	29.0 µg a.i./L	Very highly toxic

Organism	Study Type	Species	Test material	Endpoint	Value	Toxicity Category
		Bluegill sunfish (*Lepomis macrochirus*)	99% SDS-3701	96-h LC_{50}	15,000 µg a.i./L	Slightly toxic
		Rainbow trout (*Oncorhynchus mykiss*)	100% SDS-3701	96-h LC_{50}	**9,200 µg a.i./L**	Moderately toxic
	Chronic	Rainbow trout (*Oncorhynchus mykiss*)	Chlorothalonil technical	21-d NOEC	**3.0 µg a.i./L** (geometric mean)	—
		Fathead minnow (*Pimephales promelas*)	Chlorothalonil technical	Two generation (hatching success, survival)	**3.0 µg a.i./L**	—
Algae		Green algae (*Scenedesmus subspicatus*)	Chlorothalonil technical	96-h EC_{50}	310.0 µg a.i./L	—
		Green algae (*Selenastrum capricornutum*)	Chlorothalonil technical	96-h EC_{50}	116.0 µg a.i./L (geometric mean)	—
		Diatom (*Navicula pelliculosa*)	Chlorothalonil technical	120-h EC_{50}	**9.6 µg a.i./L**	—
		Blue-green algae (*Anabaena flos-aquae*)	Chlorothalonil technical	120-h EC_{50}	74.0 µg a.i./L	—
Amphibians	Acute	Japanese common toad (tadpole) (*Bufo bufo japonicus*)	Chlorothalonil technical	48-h LC_{50}	**160.0 µg a.i./L**	—
	Chronic		Chlorothalonil technical	21-d NOEC	**3.0 µg a.i./L**	—

Organism	Study Type	Species	Test material	Endpoint	Value	Toxicity Category
Marine/Estuarine Organisms						
Invertebrates	Acute	Pink shrimp *Penaeus duorarum*	Chlorothalonil technical	96-h LC_{50}	228.0 µg a.i./L (geometric mean)	Highly toxic
		Eastern oyster (embryo-larvae) *(Crassostrea virginica)*	Chlorothalonil technical	96-h EC_{50}	**11.0 µg a.i./L** (geometric mean)	Very highly toxic
	Chronic	Mysid shrimp (*Mysidopsis bahia*)	Chlorothalonil technical	Life-cycle (reproduction)	**0.83 µg a.i./L**	—
Fish	Acute	Sheepshead minnow (*Cyprinodon variegates*)	Chlorothalonil technical	96-h LC_{50}	33.0 µg a.i./L	Very highly toxic
		Threespine Stickleback (*Gasterosteus aculeatus*)	Chlorothalonil technical	96-h LC_{50}	**27.0 µg a.i./L**	Very highly toxic
		Spot (*Lieostomus xanthurus*)	Chlorothalonil technical	48-h LC_{50}	32.0 µg a.i./L	Very highly toxic
		Threespine Stickleback (*Gasterosteus aculeatus*)	100% SDS-3701	96-h LC_{50}	**4700 µg a.i./L**	Moderatel y toxic

Endpoints from fish used as surrogate.
Value in bold were used in the risk assessment.

Table 4 Screening Level Risk Assessment for Terrestrial Invertebrates

Organisms	Exposure	Endpoint Value	Application Rate	EEC[1]	RQ[2]	LOC[3] exceeded
Invertebrates						
Earthworm	Acute	14-day $LC_{50} \div 2$ 258 mg a.i./kg soil	12660 g a.i./ha × 1 9500 g a.i./ha × 4 (14 day interval)	15.7 mg a.i./kg substrate	0.06	No
Bee	Acute	48-h LD_{50} > 40 µg a.i./bee	2500 g a.i./ha × 23 (7 day interval)	6504 g a.i./ha	0.15	No

1) Environmental Exposure Concentration (Soil: calculated based on a soil density of 1.5 g/cm^3, soil depth of 15 cm and the label rates taking into consideration dissipation between applications; Bee: maximum application rate (application rate × no. of applications).
2) Risk Quotient (RQ) = exposure/toxicity
3) Level of Concern (LOC) = RQ = 1; a calculated RQ > 1 exceeds the LOC
Toxicity in µg/bee converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981; PMRA No. 1573066)
Values in bold exceed level of concern (≥1).

Table 5 Risk to Birds and Small Wild Mammals from the Consumption of Contaminated Food Items Following Applications of Chlorothalonil to Golf Course Fairways

	Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off -Field	0.06%	On-field		Off -Field	0.06%
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Application rate = 12660 g a.i./ha × 1 , 9500 g a.i./ha × 4										
Large Sized Birds (1 kg)										
Dietary	56.6	Herbivore (short grass)	625.5	**11.1**	37.5	0.7	222.1	**3.9**	13.3	0.2
Reproduction	106	Herbivore (short grass)	625.5	**5.9**	37.5	0.4	222.1	**2.1**	13.3	0.1
Medium Sized Mammal (0.035 kg)										
Reproduction	200.8	Herbivore (short grass)	1384.1	**6.9**	83.0	0.4	491.6	**2.4**	29.5	0.1
Large Sized Mammal (1 kg)										
Reproduction	200.8	Herbivore (short grass)	739.6	**3.7**	44.4	0.2	262.7	**1.3**	15.8	0.1

Values in bold exceed level of concern (≥1).

Table 6 Risk to Birds and Small Wild Mammals from the Consumption of Contaminated Food Items Following Applications of Chlorothalonil to Highbush Blueberries

	Toxicity endpoint (mg a.i./ kg bw/d)	Food Guild	Maximum nonogram residues						Mean nonogram residues					
			On-field		Off-Field	0.74%	Off-Field	0.23%	On-field		Off-Field	0.74%	Off-Field	0.23%
			EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ	EDE (mg a.i./ kg bw)	RQ
Application rate = 3600 g a.i./ha×3														
Small Bird (0.02 kg)														
Dietary	56.6	Insectivore (small insects)	361.8	**6.4**	267.7	**4.7**	83.2	**1.5**	201.8	**3.6**	149.3	**2.6**	46.4	0.8
Reproduction	106	Insectivore (small insects)	361.8	**3.4**	267.7	**2.5**	83.2	0.8	201.8	**1.9**	149.3	**1.4**	46.4	0.4
Medium Sized Bird (0.1 kg)														
Dietary	56.6	Insectivore (small insects)	282.4	**5.0**	208.9	**3.7**	64.9	**1.1**	157.5	**2.8**	116.5	**2.1**	36.2	0.6
Reproduction	106	Insectivore (small insects)	282.4	**2.7**	208.9	**2.0**	64.9	0.6	157.5	**1.5**	116.5	**1.1**	36.2	0.3
Medium Sized Mammal (0.035 kg)														
Reproduction	200.8	Herbivore (leafy foliage)	1228.8	**6.1**	909.3	**4.5**	282.6	**1.4**	406.2	**2.0**	300.6	**1.5**	93.4	0.5
Large Sized Mammal (1 kg)														
Reproduction	200.8	Herbivore (leafy foliage)	656.6	**3.3**	485.9	**2.4**	151.0	0.8	217.1	**1.1**	160.6	0.8	49.9	0.2

Values in bold exceed level of concern (≥1).

Table 7 Risk to Birds and Small Wild Mammals from the Consumption of Short Grass Contaminated with SDS-3701 Following Applications of Chlorothalonil to Turf on Golf Courses

Exposure	Organism weight (g)	FIR (g dw diet/day)	EEC (mg a.i./kg dw diet)	EDE (mg a.i./kg bw/day)	Toxicity Endpoint (mg a.i./kg bw/day)	Risk Quotient
Birds						
Acute Oral	1000	58.1	23.1	1.34	15.8	0.08
Acute Dietary	1000	58.1	23.1	1.34	18.5	0.07
Chronic	1000	58.1	23.1	1.34	2.8	0.5
Mammals						
Acute Oral	35	4.5	23.1	2.97	24.2	0.12
Acute Oral	1000	68.7	23.1	1.59	24.2	0.07
Chronic	35	4.5	23.1	2.97	0.5 (NOEL)	**5.9**
Chronic	1000	68.7	23.1	1.59	0.5 (NOEL)	**3.2**
Chronic	35	4.5	23.1	2.97	3.0 (LOEL)	0.99
Chronic	1000	68.7	23.1	1.59	3.0 (LOEL)	0.53

Values in bold exceed level of concern (≥1).

Table 8 Screening Level Risk Assessment for Aquatic Organisms

Organism	Exposure	Endpoint value[1]	Use Pattern	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Freshwater Species						
Invertebrates	Acute	HC_5 from SSD (0.019 mg a.i./L)	Golf course fairways	1.6	**84.2**	Yes
			Stone fruits	0.6	**31.6**	Yes
			Highbush blueberries	0.5	**26.3**	Yes
			Potatoes	0.2	**10.5**	Yes
Waterflea (*Daphnia magna*)	Chronic	21-d NOEC (0.039 mg a.i./L)	Golf course fairways	1.6	**41.0**	Yes
			Stone fruits	0.6	**15.4**	Yes
			Highbush blueberries	0.5	**12.8**	Yes
			Potatoes	0.2	**5.1**	Yes
Fish	Acute	HC_5 from SSD (0.013 mg a.i./L)	Golf course fairways	1.6	**123.1**	Yes
			Stone fruits	0.6	**46.2**	Yes
			Highbush blueberries	0.5	**38.5**	Yes
			Potatoes	0.2	**15.4**	Yes
Rainbow trout (*Oncorhynchus mykiss*)	Chronic	21-d NOEC (0.003 mg a.i./L)	Golf course fairways	1.6	**533.4**	Yes
			Stone fruits	0.6	**200.0**	Yes
			Highbush blueberries	0.5	**166.7**	Yes
			Potatoes	0.2	**66.7**	Yes
Green algae (*Navicula pelliculosa*)	Chronic	120-h EC_{50} (0.01 mg a.i./L)	Golf course fairways	1.6	**160.0**	Yes
			Stone fruits	0.6	**60.0**	Yes
			Highbush blueberries	0.5	**50.0**	Yes
			Potatoes	0.2	**20.0**	Yes
Amphibians (*Bufo bufo japonicus*)	Acute	48-h $LC_{50} \div 10$ (0.016 mg a.i./L)	Golf course fairways	8.4	**525.0**	Yes
			Stone fruits	3.0	**188.0**	Yes
			Highbush blueberries	2.4	**150.0**	Yes
			Potatoes	0.8	**50.0**	Yes
Amphibians[3]	Chronic	21-d NOEC (0.003 mg a.i./L)	Golf course fairways	8.4	**2800.0**	Yes
			Stone fruits	3.0	**1000.0**	Yes
			Highbush blueberries	2.4	**800.0**	Yes
			Potatoes	0.8	**266.7**	Yes

Organism	Exposure	Endpoint value[1]	Use Pattern	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Marine/Estuarine Species						
Eastern oyster (*Crassostrea virginica*)	Acute	96-h $LC_{50} \div 2$ (0.006 mg a.i./L)	Golf course fairways	1.6	**266.7**	Yes
			Stone fruits	0.6	**100.0**	Yes
			Highbush blueberries	0.5	**83.3**	Yes
			Potatoes	0.2	**33.4**	Yes
Mysid shrimp (*Mysidopsis bahia*)	Chronic	Life-cycle NOEC (0.0008 mg a.i./L)	Golf course fairways	1.6	**2000.0**	Yes
			Stone fruits	0.6	**750.0**	Yes
			Highbush blueberries	0.5	**625.0**	Yes
			Potatoes	0.2	**250.0**	Yes
Threespine Stickleback (*Gasterosteus aculeatus*)	Acute	96-h $LC_{50} \div 10$ (0.003 mg a.i./L)	Golf course fairways	1.6	**533.3**	Yes
			Stone fruits	0.6	**200.0**	Yes
			Highbush blueberries	0.5	**166.7**	Yes
			Potatoes	0.2	**66.7**	Yes

[1] Endpoints were divided by an uncertainty factor to account for varying protection goals (for example, protection at the community, population or individual level).
[2] EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.
[3] Endpoints from fish used as surrogate.
Values in bold exceed level of concern (≥1).

Table 9 Refined Risk Assessment for Aquatic Organisms (Off-field, Spray Drift)

Organism	Exposure	Endpoint value[1]	Use Pattern	RQ		
				6%	74%	23%
Freshwater Species						
Invertebrates	Acute	HC_5 from SSD (0.019 mg a.i./L)	Golf course fairways	**5.1**	—	—
			Stone fruits	—	**23.4**	**7.3**
			Highbush blueberries	—	**19.5**	**6.0**
			Potatoes	0.6	—	**2.5**
Waterflea (*Daphnia magna*)	Chronic	21-d NOEC (0.039 mg a.i./L)	Golf course fairways	**2.5**	—	—
			Stone fruits	—	**11.4**	**3.5**
			Highbush blueberries	—	**9.5**	**2.9**
			Potatoes	0.3	—	**1.2**
Fish	Acute	HC_5 from SSD (0.013 mg a.i./L)	Golf course fairways	**7.4**	—	—
			Stone fruits	—	**34.2**	**10.6**
			Highbush blueberries	—	**28.5**	**8.9**
			Potatoes	0.9	—	**3.5**
Rainbow trout (*Oncorhynchus mykiss*)	Chronic	21-d NOEC (0.003 mg a.i./L)	Golf course fairways	**32.0**	—	—
			Stone fruits	—	**148.0**	**46.0**
			Highbush blueberries	—	**123.4**	**38.3**
			Potatoes	**4.0**	—	**15.3**
Green algae (*Navicula pelliculosa*)	Chronic	120-h EC_{50} (0.01 mg a.i./L)	Golf course fairways	**9.6**	—	—
			Stone fruits	—	**44.4**	**13.8**
			Highbush blueberries	—	**37.0**	**11.5**
			Potatoes	**1.2**	—	**4.6**

Organism	Exposure	Endpoint value[1]	Use Pattern	RQ		
				6%	74%	23%
Amphibians (*Bufo bufo japonicus*)	Acute	48-h $LC_{50} \div 10$ (0.016 mg a.i./L)	Golf course fairways	**31.5**	—	—
			Stone fruits	—	**139.0**	**43.2**
			Highbush blueberries	—	**111.0**	**43.2**
			Potatoes	**3.0**	—	**11.5**
Amphibians[2]	Chronic	21-d NOEC (0.003 mg a.i./L)	Golf course fairways	**168.0**	—	—
			Stone fruits	—	**740.0**	**230.0**
			Highbush blueberries	—	**592.0**	**184.0**
			Potatoes	**16.0**	—	**61.3**
Marine/Estuarine Species						
Eastern oyster (*Crassostrea virginica*)	Acute	96-h $LC_{50} \div 2$ (0.006 mg a.i./L)	Golf course fairways	**16.0**	—	—
			Stone fruits	—	**74.0**	**23.0**
			Highbush blueberries	—	**61.6**	**19.2**
			Potatoes	**2.0**	—	7.7
Mysid shrimp (*Mysidopsis bahia*)	Chronic	Life-cycle NOEC (0.0008 mg a.i./L)	Golf course fairways	**120.0**	—	—
			Stone fruits	—	**555.0**	**172.5**
			Highbush blueberries	—	**462.5**	**143.8**
			Potatoes	**15.0**	—	**57.5**
Threespine Stickleback (*Gasterosteus aculeatus*)	Acute	96-h $LC_{50} \div 10$ (0.003 mg a.i./L)	Golf course fairways	**32.0**	—	—
			Stone fruits	—	**148.0**	**46.0**
			Highbush blueberries	—	**123.4**	**38.3**
			Potatoes	**4.0**	—	**15.3**

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (for example, protection at the community, population, or individual level).
[2] Endpoints from fish used as surrogate.
Values in bold exceed Level of concern (≥ 1).

Table 10 Refined Risk Assessments for Aquatic Organisms (Run-off)

Organism	Endpoint value[1]	Scenario	EEC (mg a.i./L)[2]	RQ	LOC Exceeded
Freshwater Species					
Golf course fairways					
Invertebrates	Acute HC_5 from SSD (0.019 mg a.i./L)	Okanagan B.C.	0.003	0.2	No
		Prairie Regions	0.2	**10.5**	Yes
Waterflea (*Daphnia magna*)	Chronic 21-d NOEC (0.039 mg a.i./L)	Okanagan B.C.	0.0002	0.005	No
		Atlantic Region	0.02	0.5	No
Fish	Acute HC_5 from SSD (0.013 mg a.i./L)	Okanagan B.C.	0.003	0.2	No
		Prairie Regions	0.2	**15.4**	Yes
Rainbow trout (*Oncorhynchus mykiss*)	Chronic 21-d NOEC (0.003 mg a.i./L)	Okanagan B.C.	0.0002	0.07	No
		Atlantic Region	0.02	**6.7**	Yes
Green algae (*Navicula pelliculosa*)	Chronic 120-h EC_{50} (0.01 mg a.i./L)	Okanagan B.C.	0.001	0.1	No
		Atlantic Region	0.07	**7.0**	Yes

Organism	Endpoint value[1]	Scenario	EEC (mg a.i./L)[2]	RQ	LOC Exceeded
Amphibians (*Bufo bufo japonicus*)	Acute 48-h $LC_{50} \div 10$ (0.016 mg a.i./L)	Okanagan B.C.	0.02	**1.3**	Yes
		Prairie Regions	0.8	**50.0**	Yes
Amphibians[3]	Chronic 21-d NOEC (0.003 mg a.i./L)	Okanagan B.C.	0.001	0.3	No
		Atlantic Region	0.07	**23.3**	Yes
Highbush Blueberries					
Invertebrates	Acute HC_5 from SSD (0.019 mg a.i./L)	British Columbia	0.01	0.5	No
		Atlantic Region	0.07	**3.7**	Yes
Waterflea (*Daphnia magna*)	Chronic 21-d NOEC (0.039 mg a.i./L)	British Columbia	0.002	0.05	No
		Atlantic Region	0.004	0.1	No
Fish	Acute HC_5 from SSD (0.013 mg a.i./L)	British Columbia	0.01	0.8	No
		Atlantic Region	0.07	**5.4**	Yes
Rainbow trout (*Oncorhynchus mykiss*)	Chronic 21-d NOEC (0.003 mg a.i./L)	British Columbia	0.002	0.7	No
		Atlantic Region	0.004	**1.3**	Yes
Green algae (*Navicula pelliculosa*)	Chronic 120-h EC_{50} (0.01 mg a.i./L)	British Columbia	0.007	0.7	No
		Atlantic Region	0.02	**2.0**	Yes
Amphibians (*Bufo bufo japonicus*)	Acute 48-h $LC_{50} \div 10$ (0.016 mg a.i./L)	British Columbia	0.07	**4.4**	Yes
		Atlantic Region	0.35	**22.0**	Yes
Amphibians[3]	Chronic 21-d NOEC (0.003 mg a.i./L)	British Columbia	0.007	**2.3**	Yes
		Atlantic Region	0.02	**6.7**	Yes
Potatoes					
Invertebrates	Acute HC_5 from SSD (0.019 mg a.i./L)	Prairie Region	0.1	**5.3**	Yes
		Atlantic Region	0.1	**5.3**	Yes
Waterflea (*Daphnia magna*)	Chronic 21-d NOEC (0.039 mg a.i./L)	Prairie Region	0.01	0.3	No
		Atlantic Region	0.02	0.5	No
Fish	Acute HC_5 from SSD (0.013 mg a.i./L)	Prairie Region	0.1	**7.7**	Yes
		Atlantic Region	0.1	**7.7**	Yes
Rainbow trout (*Oncorhynchus mykiss*)	Chronic 21-d NOEC (0.003 mg a.i./L)	Prairie Region	0.01	**3.4**	Yes
		Atlantic Region	0.02	**6.7**	Yes
Green algae (*Navicula pelliculosa*)	Chronic 120-h EC_{50} (0.01 mg a.i./L)	Prairie Region	0.035	**3.5**	Yes
		Atlantic Region	0.043	**4.3**	Yes

Organism	Endpoint value[1]	Scenario	EEC (mg a.i./L)[2]	RQ	LOC Exceeded
Amphibians (*Bufo bufo japonicus*)	Acute 48-h $LC_{50} \div 10$ (0.016 mg a.i./L)	Prairie Region	0.54	**33.8**	Yes
		Atlantic Region	0.55	**34.4**	Yes
Amphibians[3]	Chronic 21-d NOEC (0.003 mg a.i./L)	Prairie Region	0.04	**13.4**	Yes
		Atlantic Region	0.07	**23.4**	Yes
Estuarine/Marine Species					
Golf Course Fairways					
Eastern oyster (*Crassostrea virginica*)	Acute 96-h $LC_{50} \div 2$ (0.006 mg a.i./L)	Lower B.C.	0.1	**16.7**	Yes
		Atlantic Region	0.16	**26.7**	Yes
Mysid shrimp (*Mysidopsis bahia*)	Chronic Life-cycle NOEC (0.0008 mg a.i./L)	Lower B.C.	0.01	**12.5**	Yes
		Atlantic Region	0.02	**25.0**	Yes
Threespine Stickleback (*Gasterosteus aculeatus*)	Acute 96-h $LC_{50} \div 10$ (0.003 mg a.i./L)	Lower B.C.	0.1	**33.4**	Yes
		Atlantic Region	0.16	**53.3**	Yes
Highbush Blueberries					
Eastern oyster (*Crassostrea virginica*)	Acute 96-h $LC_{50} \div 2$ (0.006 mg a.i./L)	British Columbia	0.013	**2.2**	Yes
		Atlantic Region	0.07	**11.7**	Yes
Mysid shrimp (*Mysidopsis bahia*)	Chronic Life-cycle NOEC (0.0008 mg a.i./L)	British Columbia	0.002	**2.5**	Yes
		Atlantic Region	0.004	**5.0**	Yes
Threespine Stickleback (*Gasterosteus aculeatus*)	Acute 96-h $LC_{50} \div 10$ (0.003 mg a.i./L)	British Columbia	0.013	**4.4**	Yes
		Atlantic Region	0.07	**23.4**	Yes
Potatoes					
Eastern oyster (*Crassostrea virginica*)	Acute 96-h $LC_{50} \div 2$ (0.006 mg a.i./L)	Atlantic Region	0.1	**16.7**	Yes
Mysid shrimp (*Mysidopsis bahia*)	Chronic Life-cycle NOEC (0.0008 mg a.i./L)	Atlantic Region	0.02	**25.0**	Yes
Threespine Stickleback (*Gasterosteus aculeatus*)	Acute 96-h $LC_{50} \div 10$ (0.003 mg a.i./L)	Atlantic Region	0.1	**33.3**	Yes

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (for example, protection at the community, population or individual level).
[2] EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.
[3] Endpoints from fish used as surrogate.
Values in bold exceed Level of concern (≥ 1).

Table 11 Risk Assessment for Aquatic Organisms (Monitoring Data)

Organism	Endpoint value[1]	EEC (mg a.i./L)[2]	RQ	LOC Exceeded
Freshwater Species				
Invertebrates	Acute HC_5 from SSD (0.019 mg a.i./L)	0.037	**1.9**	Yes
Waterflea (*Daphnia magna*)	Chronic 21-d NOEC (0.039 mg a.i./L)	0.0001	0.003	No
Fish	Acute HC_5 from SSD (0.013 mg a.i./L)	0.037	**2.9**	Yes
Rainbow trout (*Oncorhynchus mykiss*)	Chronic 21-d NOEC (0.003 mg a.i./L)	0.0001	0.03	No
Green algae (*Navicula pelliculosa*)	Chronic 120-h EC_{50} (0.01 mg a.i./L)	0.037	**3.7**	Yes
Amphibians[3]	Acute 96-h $LC_{50} \div 10$ (0.002 mg a.i./L)	0.037	**18.5**	Yes
Amphibians[3]	Chronic 21-d NOEC (0.003 mg a.i./L)	0.0001	0.03	No
Marine/Estuarine Species				
Eastern oyster (*Crassostrea virginica*)	Acute 96-h $LC_{50} \div 2$ (0.006 mg a.i./L)	0.037	**6.2**	Yes
Mysid shrimp (*Mysidopsis bahia*)	Chronic Life-cycle NOEC (0.0008 mg a.i./L)	0.0001	0.1	No
Threespine Stickleback (*Gasterosteus aculeatus*)	Acute 96-h $LC_{50} \div 10$ (0.003 mg a.i./L)	0.037	**12.3**	Yes

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (for example, protection at the community, population or individual level).
[2] EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.
[3] Endpoints from fish used as surrogate.
Values in bold exceed Level of concern (≥ 1).

Table 12 Acute risk to freshwater fish from maximum concentrations of chlorothalonil in surface water estimated from available Canadian monitoring data

Location	Absolute Maximum Concentration (µg/L)	Toxicity endpoint (Fish HC_5 from SSD) (µg/L)	Risk Quotient
New Brunswick 2008	32.4	13.0	**2.5**
New Brunswick (Little River 2006)	39.8	13.0	**3.1**
New Brunswick (Little River 2007)	20.8	13.0	**1.6**
New Brunswick (Little River 2008)	24.3	13.0	**1.9**
P.E.I. 2007	22.9	13.0	**1.8**
P.E.I. 2008	32.4	13.0	**2.5**
New Brunswick (Black Brook Weir #1 2006)	312.1	13.0	**24.0**
New Brunswick (Black Brook Weir #1 2007)	19.0	13.0	**1.5**
New Brunswick (Black Brook Weir #1 2008)	60.9	13.0	**4.7**

Values in bold exceed Level of concern (≥ 1).

Table 13 Toxic Substances Management Policy (TSMP) Considerations - Comparison to Toxic Substances Management Policy

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		—
Predominantly anthropogenic[2]	Yes		—
Persistence[3]:	Soil	Half-life ≥ 182 days	Half-life 3 – 59 days
	Water	Half-life ≥ 182 days	Half-life 0.5 – 0.85 days
	Sediment	Half-life ≥ 365 days	Half-life 5.9 – 9.3 days
	Air	Half-life ≥ 2 days or evidence of long range transport	Found in air samples in the Arctic

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Active Ingredient Endpoints
Bioaccumulation[4]	Log $K_{OW} \geq 5$	2.88
	BCF $\geq$ 5000	4,500 (rainbow trout)
	BAF $\geq$ 5000	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (that is, all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

4 Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Appendix IX Chlorothalonil Aquatic Ecoscenario Assessment

1.0 Introduction

The following sections provide review the estimated environmental concentrations (EECs) of chlorothalonil resulting from water modelling and the available water monitoring data with respect to environmental exposure.

Monitoring data and modelling estimates provide different types of information, therefore are not directly comparable. Pesticide concentrations in water are highly variable in time and location, and Canadian monitoring data usually are sparse, so comparing monitoring results to modelling is not straightforward. Despite this, these two types of data are complementary and should be considered in conjunction with each other when considering the potential exposure of aquatic organisms or to humans through drinking water.

2.0 Modelling Estimates

2.1 Aquatic Ecoscenario Assessment: Level 1 Modelling

Chlorothalonil is a fungicide used on a variety of uses, including asparagus, blueberries, carrots, cole crops, cranberry, onions, potatoes, strawberry, sweet corn, tomato, wheat, golf courses, conifers and ornamentals. According to registrant information on use pattern for chlorothalonil, the maximum annual application rate for use on golf course fairways is 5 applications at 14 day interval with the first application of 12.66 kg a.i./ha and four applications of 9.5 kg a.i./ha (maximum of 50.66 kg a.i./ha). Additional crops were modeled in order to cap the risk. These included potatoes with an application rate of 1.2 kg a.i./ha × 12 applications with 7 day intervals (maximum of 14.4 kg a.i./ha); and blueberries with an application rate of 3.6 kg a.i./ha × 3 applications (for highbush) and 2 applications (for lowbush) with 7 day intervals (maximum rate of 10.8 kg a.i./ha). Application information and the main environmental fate characteristics used in the models are summarized in Table 1.

Table 1 Major Ecoscenario Water Model Inputs for Level 1 Assessment of Chlorothalonil

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Asparagus, blueberries, carrots, cole crops, cranberry, onions, potatoes, strawberry, sweet corn, tomato, wheat, golf courses, conifers, ornamentals
	Maximum allowable application rate per year (g a.i./ha)	50660 for golf course fairway 14400 for potato 10800 for blueberry
	Maximum rate each application (g a.i./ha)	12660 for the first and 9500 for the following four applications for golf course fairway 1200 for potato 3600 for blueberry
	Maximum number of applications per year	5 for golf course fairway 12 for potato 3 for highbush blueberry 2 for lowbush blueberry
	Minimum interval between applications (days)	14 for golf course fairway 7 for potato 7 for blueberry
	Method of application	Foliar
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	Stable
	Photolysis half-life in water (days)	65
	Adsorption K_d (mL/g)	16.6 (20^{th} percentile of four K_d values for "chlorothalonil")
	Aerobic soil biotransformation half-life (days)	28.7 (80^{th} percentile of five half-life values)
	Aerobic aquatic biotransformation half-life (days)	0.5 (the only value in the entire system from fresh water study)
	Anaerobic aquatic biotransformation half-life (days)	11.6 (80^{th} percentile of four half-life values)

For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of chlorothalonil from run-off into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide run-off from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m.

A total of ten standard regional scenarios were modelled to represent different regions of Canada. Up to ten initial application dates between March and July (which vary with scenarios and regions) were modelled. Table 1 lists the application information and the main environmental fate characteristics used in the simulations. The EECs are for the portion of the pesticide that enters the water body via run-off only; deposition from spray drift is not included. The models were run for 50 years for all scenarios.

The EECs are calculated from the model output from each run as follows. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day and 1 year). The 90th percentiles over each averaging period are reported as the EECs for that period.

The largest EECs of all selected runs of a given use pattern/regional scenario are reported in Table 2 for a water body of 0.8 m and Table 3 for a water body of 0.15 m deep, respectively.

Table 2 Level 1 Aquatic Ecoscenario Modelling EECs (μg a.i./L) for Chlorothalonil in a Water Body 0.8 m Deep, Excluding Spray Drift

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Golf course fairway: (1 × 12.66 + 4 × 9.5) kg a.i./ha, at 14 day intervals						
Lower mainland BC	99	44	9.6	3.7	2.5	0.61
Okanagan BC	3.3	1.1	0.21	0.075	0.050	0.012
Prairie Regions	214	61	14	5.1	3.4	0.84
ON	130	34	6.7	2.8	2.1	0.51
QC	86	26	7.3	2.7	1.8	0.45
Atlantic Region	161	65	18	6.7	4.5	1.1
Blueberry: 3 × 3.6 (2 × 3.6 for Atlantic Regions) kg a.i./ha, at 7 day intervals						
BC	13	6.7	1.7	0.63	0.42	0.10
ON	41	12	2.8	1.2	0.81	0.20
QC	32	9.2	2.1	0.77	0.54	0.14
Atlantic Region	66	18	3.8	1.4	1.0	0.26
Potato: 12 × 1.2 kg a.i./ha, at 7 day intervals						
Prairie Region	103	35	10	5.2	3.6	0.94
Atlantic Region	104	43	18	9.8	7.5	2.1

Table 3 Level 1 Aquatic Ecoscenario Modelling EECs (μg a.i./L) for Chlorothalonil in a Water Body 0.15 m Deep, Excluding Spray Drift

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Golf course fairway: (1 × 12.66 + 4 × 9.5) kg a.i./ha, at 14 day intervals						
Lower mainland BC	491	190	41	16	11	27
Okanagan BC	18	4.7	0.99	0.36	0.24	0.059
Prairie Regions	1143*	278	65	24	16	3.9
ON	694	151	32	13	10	2.5
QC	458	118	30	11	7.6	1.9
Atlantic Region	861*	277	72	29	20	4.9
Blueberry: 3 × 3.6 (2 × 3.6 for Atlantic Regions) kg a.i./ha, at 7 day intervals						
BC	70	28	6.6	2.7	1.8	0.46
ON	220	53	13	5.6	3.9	0.97
QC	171	42	9.7	3.7	2.6	0.65
Atlantic Region	349	83	18	6.6	5.0	1.27
Potato: 12 × 1.2 kg a.i./ha, at 7 day intervals						
Prairie Region	545	156	44	24	17	4.5
Atlantic Region	553	188	72	43	33	9.9

* These EECs are greater than the reported solubility of 810 μg a.i./L of chlorothalonil in water. This is an artefact of having to run the water models using a value for the limit of solubility which was up to 10 fold the actual value in order for the water model EXAMS to run (EXAMS will not run if EECs exceeds 50% of its (aqueous) solubility).

3.0 Water Monitoring data

3.1 Sources of Data

A search for chlorothalonil water monitoring data in Canada resulted in a number of samples with detections being reported. The Federal Provincial and Territorial representatives from all of the provinces and territories in Canada were contacted, requesting water monitoring data for the pesticides that are currently under re-evaluation. In addition, requests were submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. A response was received indicating that either monitoring data were not available or the available data were submitted.

For the purposes of the environmental risk assessment of chlorothalonil, US databases were searched for detections of chlorothalonil. Data on residues present in water samples taken in the US are important to consider in the Canadian water assessment given the extensive monitoring programs that exist in the US. Run-off events, local use patterns, site specific hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and applications may be more numerous and frequent.

As the re-evaluation of chlorothalonil is being done under Program 1 for the human health portion of the risk assessment, monitoring data in drinking water sources from the US were not considered in the drinking water assessment, as these data were already considered in the US EPA RED on which the re-evaluation of risk to human health is based. Also, acute and chronic exposure estimates in water were calculated for the ecoscenario assessment but not for the drinking water assessment. The available monitoring data for chlorothalonil are summarized in Table 4. They provide an indication of the potential impact of chlorothalonil on Canadian water resources.

3.2 Approach for Evaluation

Data from Canadian and US water monitoring studies in which chlorothalonil was quantified are summarized in Table 4.

For both the ecoscenario assessment and the drinking water assessment, information was extracted from the available sources, tabulated and sorted into categories as follows:

1. Residues in known drinking water sources (both surface and groundwater)
2. Residues in ambient water that may serve as a drinking water source (both surface and groundwater)
3. Residues in ambient water that are unlikely to serve as a drinking water source

An important limitation of the monitoring data set is that, in many cases, the data were not accompanied with use data for chlorothalonil. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of inappropriate timing of sampling. In addition, because the data are sparse and concentrations vary in time and space, the maximum concentration reported is unlikely to be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates, precipitation and some areas/soils are simply more prone to leaching and/or run-off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

Thus, it is likely chlorothalonil was not used in some of the areas monitored and that higher concentrations of chlorothalonil may occur in other areas not monitored. The chlorothalonil monitoring data likely underestimate the peak exposure because of the following limitations:

1. In general, the data are sparse in both time and location. In some of the studies available, chlorothalonil was analyzed in samples that were taken from non-chlorothalonil use areas. Chlorothalonil use information from the areas surrounding where the samples were collected is often not available.

2. Sampling in some of the studies was conducted during periods when chlorothalonil is not applied in Canada (for example, October through March).

3. The concentrations of pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and run-off events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. Samples are often taken at arbitrary time intervals (for example, once a month, once a week) and are unlikely to capture the absolute maximum concentration of chlorothalonil.

The following statistics are used to interpret the information available in each dataset and are summarized in Table 4.

- The detection frequency provides an indication of how often positive detections occur within the given data set. Detection frequency is primarily determined by the limits of detection and is influenced by pesticide use patterns and application rates. Consequently, a wide range of detection frequencies is likely to be expected.

- The 95th percentile concentration is calculated and reported. Maximum values should also be considered, especially when the 95th percentile is not available which occurs when there are insufficient detections to calculate a 95th percentile.

- The maximum concentration is reported and is used to determine the 95th percentile concentration to estimate and acute exposure value (for the ecoscenario assessment only).

- The arithmetic mean with non-detects considered at ½ LOD is used to determine the 95th percentile concentrations to estimate a chronic exposure value (for the ecoscenario assessment only).

Table 4 Summary of the Monitoring Studies Available

Data Source	DETECTION FREQUENCY						CONCENTRATION (µg/L)			
	Location		Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
Chlorothalonil residues in municipal drinking water sources and ground water										
PMRA 1311142, 1311143	Treated water, Alberta (1995-2003)		0.005	13	0	0	—	—	—	0.0025
PMRA 1650553	Treated water, Alberta (1995-2007) (may include the samples from 1311142, 1311143)		0.005	298	0	0	—	—	—	0.0025
PMRA 1346006	PEI 1990-1991 (not used due to missing information)		NR	2	0	0	—	—	—	—
PMRA 1737520	PEI Groundwater	2003	0.1	110	2	1.8	0.25	—	0.4	0.054
		2004	0.02	108	1	0.93	—	—	0.7	0.016
		2005	0.02	105	0	0	—	—	—	0.01
		2006	0.02	96	0	0	—	—	—	0.01
		2007	0.02	103	0	0	—	—	—	0.01
		2008	0.02	103	5	4.85	0.046	0.076	0.08	0.012
PMRA 1311111, 1311112	Groundwater; British Columbia Lower Fraser Valley (2003-2004)		0.000001	11	9	82	—	—	0.000031	—
PMRA 1307578	Wells in apple growing region of Quebec (1994-1996)		0.06	42	0	0	—	—	—	0.03
PMRA 1763866	Nova Scotia groundwater (2008)		0.04	26	1	3.8	—	—	0.09	0.023
	New Brunswick groundwater (2008)		0.025-0.04	22	0	0	—	—	—	0.016

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1560632, 1640595	New Brunswick Municipal Drinking Water supplies (ground and surface water – 2003)			0.01-0.3	10	0	0	—	—	—	0.092
PMRA 1311119, 1311120	Private wells in the potato growing region of Quebec (1999-2001)			0.05-0.02	123 samples in 79 wells	4	3.3	0.02	0.02	0.02	0.015
Chlorothalonil residues in ambient water that may serve as a drinking water source											
PMRA 1311104	Surface water, British Columbia	Agriculture		NR	6	6	100	0.0018	0.0057	0.0069	0.0018
		Urban		NR	2	2	100	0.017	0.03	0.0319	0.017
		Urban/Agriculture		NR	4	4	100	0.005	0.015	0.0169	0.005
PMRA 1311111, 1311112	Lower Fraser Valley, British Columbia (2003-2004)			0.000001	14	14	100	—	—	0.036	—
	Okanagan Basin, British Columbia (2003-2004)			0.000009	7	3	43	—	—	0.0002	—
	Quebec	Yamaska River	2003	0.06	14	1	7.14	—	—	0.1	0.035
			2004	0.06	12	0	0	—	—	—	0.03
		Nicolet River	2003	0.06	15	0	0	—	—	—	0.03
			2004	0.06	14	0	0	—	—	—	0.03
		Saint-François River	2003	0.06	12	1	8.3	—	—	4.2	0.378
			2004	0.06	13	0	0	—	—	—	0.03
		Saint-Lawrence River at Quebec City	2004	0.06	15	0	0	—	—	—	0.03

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
		Saint-Lawrence River at Port Saint-François	2003	0.06	8	0	0	—	—	—	0.03
			2004	0.06	16	0	0	—	—	—	0.03
PMRA 1307571	Corn and Soya bean region of Quebec	Chibouet River	1999	0.06	45	0	0.0	—	—	—	0.03
			2000	0.08	40	0	0.0	—	—	—	0.04
			2001	0.06	46	1	2.2	—	—	0.11	0.03
		des Hurons River	1999	0.06	45	0	0.0	—	—	—	0.03
			2000	0.08	42	0	0.0	—	—	—	0.04
			2001	0.06	44	0	0.0	—	—	—	0.03
		Saint-Régis River	1999	0.06	45	1	2.2	—	—	0.07	0.03
			2000	0.08	43	1	2.3	—	—	0.2	0.04
			2001	0.06	45	0	2.2	—	—	—	0.03
		Saint-Zéphirin River	1999	0.06	45	0	0.0	—	—	—	0.03
			2000	0.08	43	0	0.0	—	—	—	0.04
			2001	0.06	46	0	0.0	—	—	—	0.03
		Yamaska River	1999	0.06	45	2	4.4	0.06	0.06	0.06	0.03
			2000	0.08	43	0	0.0	—	—	—	0.04
			2001	0.06	46	1	2.2	—	—	0.37	0.04

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1398451, 1398452, 1398453	Corn and Soya bean region of Quebec	Chibouet River	2002	0.06	43	0	0.0	—	—	—	0.03
			2003	0.06	41	0	0.0	—	—	—	0.03
			2004	0.06	41	1	2.4	—	—	0.06	0.03
		des Hurons River	2002	0.06	42	0	0.0	—	—	—	0.03
			2003	0.06	41	0	0.0	—	—	—	0.03
			2004	0.06	41	0	0.0	—	—	—	0.03
		Saint-Régis River	2002	0.06	40	0	0.0	—	—	—	0.03
			2003	0.06	39	0	0.0	—	—	—	0.03
			2004	0.06	39	0	0.0	—	—	—	0.03
		Saint-Zéphirin River	2002	0.06	42	0	0.0	—	—	—	0.03
			2003	0.06	39	0	0.0	—	—	—	0.03
			2004	0.06	39	0	0.0	—	—	—	0.03
PMRA 1307568	Corn and Soya bean region of Quebec	Chibouet River	1996	0.06	40	0	0.0	—	—	—	0.03
			1997	0.06	37	0	0.0	—	—	—	0.03
			1998	0.06	42	0	0.0	—	—	—	0.03
		des Hurons River	1996	0.06	41	0	0.0	—	—	—	0.03
			1997	0.06	39	0	0.0	—	—	—	0.03

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
			1998	0.06	45	0	0.0	—	—	—	0.03
		Saint-Régis River	1996	0.06	41	0	0.0	—	—	—	0.03
			1997	0.06	40	0	0.0	—	—	—	0.03
			1998	0.06	51	0	0.0	—	—	—	0.03
		Saint-Zéphirin River	1996	0.06	39	0	0.0	—	—	—	0.03
			1997	0.06	39	0	0.0	—	—	—	0.03
			1998	0.06	48	0	0.0	—	—	—	0.03
		Yamaska River	1996	0.06	17	0	0.0	—	—	—	0.03
			1997	0.06	8	0	0.0	—	—	—	0.03
			1998	0.06	49	0	0.0	—	—	—	0.03

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1307569	Corn and Soya bean region of Quebec	Saint-Zéphirin River	1994	0.06	37	0	0.0	—	—	—	0.03
			1995	0.06	38	0	0.0	—	—	—	0.03
		Chibouet River	1994	0.06	45	0	0.0	—	—	—	0.03
			1995	0.06	38	0	0.0	—	—	—	0.03
		des Hurons River	1994	0.06	47	0	0.0	—	—	—	0.03
			1995	0.06	34	0	0.0	—	—	—	0.03
		Saint-Régis River	1994	0.06	34	0	0.0	—	—	—	0.03
			1995	0.06	35	0	0.0	—	—	—	0.03
		Saint-Esprit River	1994	0.06	9	0	0.0	—	—	—	0.03
			1995	0.06	6	0	0.0	—	—	—	0.03
		des Anges River	1994	0.06	10	0	0.0	—	—	—	0.03
			1995	0.06	2	0	0.0	—	—	—	0.03
		Bayonne River	1994	0.06	9	0	0.0	—	—	—	0.03
		Noire River	1994	0.06	6	0	0.0	—	—	—	0.03
		Yamaska River	1994	0.06	8	0	0.0	—	—	—	0.03
			1995	0.06	2	0	0.0	—	—	—	0.03

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
		Nicolet River	1994	0.06	4	0	0.0	—	—	—	0.03
		Châteauguay River	1994	0.06	1	0	0.0	—	—	—	0.03
PMRA 1307578	Streams in apple growing region of Quebec	Déversant stream	1994	0.06	12	0	0.0	—	—	—	0.03
			1995	0.06	15	0	0.0	—	—	—	0.03
			1996	0.06	23	0	0	—	—	—	0.03
		Boffin stream	1994	0.06	12	0	0	—	—	—	0.03
			1995	0.06	13	0	0	—	—	—	0.03
			1996	0.06	24	0	0	—	—	—	0.03
		Abbott's Corner stream	1994	0.06	12	0	0	—	—	—	0.03
PMRA 1307581	Quebec	Corbin stream	1996	0.06	17	0	0	—	—	—	0.03
			1997	0.06	34	0	0	—	—	—	0.03
		Saint-Pierre stream	1996	0.06	1	0	0	—	—	—	0.03
		de l'Achigan River	1996	0.06	18	0	0	—	—	—	0.03
			1997	0.06	29	0	0	—	—	—	0.03

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1763866 (encompasses data from 1311111, 1311112, 1726638 and 1726642)	Atlantic Region, surface water	Nova Scotia	2004	0.01	19	0	0	—	—	—	0.005
			2005	0.02	27	2	7.4	0.03	0.03	0.03	0.011
			2008-wet	0.04	4	0	0	—	—	—	0.02
			2008-dry	0.04	2	0	0	—	—	—	0.02
		New Brunswick	2003	0.05	23	4	17.4	4.7	4.9	4.9	0.829
			2004	0.01	17	4	23.5	1.17	1.60	1.68	0.281
			2005	0.02	12	1	8.3	—	—	0.02	0011
			2008-wet	0.04	12	2	16.7	17.81	30.9	32.38	—
			2008-dry	0.04	5	0	0	—	—	—	0.02
		Little River Weir #12, New Brunswick	2006	0.025	5 samples from 7 run-off events	5	100	—	—	39.78	—
			2007	0.025	25 samples from 5 events	13	52	—	—	20.79	—
			2008-wet	0.04	68	23	33.8	—	—	24.32	—
PMRA 1311118	Alberta surface water (1995-2002)			0.005	42	0	0	—	—	—	0.0025
PMRA 1311130	Manitoba (1990-2001) (not used as limit of detection is too high)			0.5-10.0	481	0	0	—	—	—	—

Data Source	DETECTION FREQUENCY						CONCENTRATION (µg/L)			
	Location		Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1311131	Manitoba (2001-2003)		0.06-0.2	283	0	0	—	—	—	0.038
PMRA 1650553	Alberta untreated surface water (1995-2007) (may include the samples from 1311118)		0.005	645	0	0	—	—	—	0.0025
PMRA 1311133, 1311134	Floodway and Red River at Selkirk, and south basin of Lake Winnipeg, Manitoba (1997)		0.00162	44	0	0	—	—	—	0.0008
PMRA 1703710	Quebec (2003-2007)		0.005-0.06	325	2	0.6	2.2	4.0	4.2	0.037
PMRA 1703704	New Brunswick (1986-1998)		0.001-0.008	15	0	0	—	—	—	0.0035
PMRA 1739329	Surface water in British Columbia (2003-2005)	Reference site CHK	0.00064	1	1	100	—	—	0.000065	0.000065
		Reference site HAS	0.00026-0.00006	4	0	0	—	—	—	—
		Reference site MUR	0.000001-0.00038	4	2	50	—	—	0.000122	—
		Urban site SCT	0.000064	4	4	100	—	—	0.00214	—
		Urban site MOS	0.00047	5	3	60	—	—	0.00024	—
PMRA 1719667	surface water from NAWQA database (HPLC Method); United States (1993-2005)		0.007-1.8393	7097	25	0.4	0.151	0.676	0.71	0.047
PMRA 1719668	surface water from NAWQA database (no method); United States (1993) (not used)		0.07	87	3	3.5	0.093	0.117	0.12	0.037
PMRA 1619184	Surface water,	Oak Newel	NR	NR	NR	64	0.0015	—	0.0134	—

Data Source	DETECTION FREQUENCY						CONCENTRATION (µg/L)			
	Location		Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
	United States (2000-2002)	Keg Creek	NR	NR	NR	65	0.00806	—	0.17191	—
		Stoney Brook	NR	NR	NR	70	0.0007	—	0.00821	—
		Crabapple	NR	NR	NR	68	0.00412	—	0.07413	—
		Smoke Rise	NR	NR	NR	70	0.00184	—	0.02157	—
		Cherry Branch	NR	NR	NR	74	0.00238	—	0.03005	—
Chlorothalonil residues in water that is unlikely to be used as drinking water sources										
PMRA 1311123	station d'épuration de Laval (2001)		0.06	25	1	4.0	—	—	0.16	0.04
	station d'épuration de Repentigny (2001)		0.06	27	0	0.0	—	—	—	0.03
	station d'épuration de la CUQ (station est) (2001)		0.06	27	1	3.7	—	—	0.26	0.04
	station d'épuration de la CUQ (station ouest) (2001)		0.06	28	1	3.6	—	—	0.06	0.03
	station d'épuration de Saint-Hyacinthe (2002)		0.06	27	0	0.0	—	—	—	0.03
	station d'épuration de Granby (2002)		0.06	29	1	3.4	—	—	0.43	0.04
	station d'épuration de Sherbrooke (2002)		0.06	30	0	0.0	—	—	—	0.03
	Run-off from rain event in waterbodies present Quebec's urban communities (May 28, 2001)		0.06	24	0	0	—	—	—	0.03
PMRA 1307566	PEI surface water (1996)		NR	13	1	7.69	—	—	0.078	—

Data Source	DETECTION FREQUENCY							CONCENTRATION (µg/L)			
	Location			Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1703704, encompasses data from 1311126	PEI surface water (1986-1998)			0.0002-0.035	109	9	8.26	0.04	0.19	0.311	0.01
PMRA 1763866 (encompasses data from 1311111, 1311112, 1726638 and 1726642)	PEI- surface water		2003	0.025	27	1	3.7	—	—	0.64	0.036
			2004	0.025	21	7	33.3	7.2	9.2	9.65	2.41
			2005	0.05	40	0	0	—	—	—	0.025
			2006	0.01-0.025	127	7	5.5	—	—	5.92	—
			2007	0.025	129	22	17.1	—	—	22.92	—
			2008-wet	0.04	67	2	3.0	17.8	30.9	32.38	0.551
			2008-dry	0.04	7	0	0	—	—	—	0.02
	New Brunswick	Black Brook, Weir #1	2006	0.025	77 samples from 12 events	37	48.1	—	—	312.1	—
			2007	0.025	28 samples from 5 events	9	32.1	—	—	19.02	—
			2008-wet	0.04	74	30	40.5	—	—	60.93	—
		Black Brook Sub-Basin, Weir #9 (not used as not represent-tative of aquatic habitat or drinking water source)	2006	0.025	41 samples from 10 events	41	100	—	—	1851	—
			2007	0.025	13 samples from 4 events	7	53.8	—	—	218	—
			2008-wet	0.04	65	34	52.3	—	—	190.5	—

Data Source	DETECTION FREQUENCY					CONCENTRATION (µg/L)			
	Location		Min detection or detection limit (µg/L)	# of systems tested (or absolute number of samples)	# of systems or samples with detections	% Detection frequency	Mean detection	95th centile	Absolute Max	Arithmetic Mean Including non-detects at ½ LOD
PMRA 1311124	Four irrigation canals in southern Alberta	1999	0.05	20	0	0	—	—	—	0.025
PMRA 1311111, 1311112	British Columbia – Lower Fraser Valley (run-off)		NR	13	1	7.7	—	—	—	—
PMRA 1311126	PEI (not used as already in 1703704)		NR	108	NR	4	—	—	0.311	—
PMRA 1774484	Untreated raw water intake for water treatment plants, United States (2007)		0.00005	118	0	0	—	—	—	0.000025

3.3 Ecoscenario Exposure Estimates from Monitoring Data

The acute and chronic exposure estimates for chlorothalonil in surface water are presented in Table 5. The acute exposure value was estimated from monitoring data by determining the 95th percentile of the maximum concentration detected in each monitoring study/site. The chronic exposure value was estimated by determining the 95th percentile of the arithmetic means of all samples at each site (detects and non-detects) from the monitoring studies. The samples with values less than the LOD were given a value of ½ LOD. Groundwater data and data from water distribution systems were not included in the ecoscenario assessment. Uncertainties associated with the data are provided in Section 3.1.

Table 5 Concentrations of Chlorothalonil in Surface Water Estimated from Available Monitoring Data

Acute Concentration (µg/L)[1]	Chronic Concentration (µg/L)[2]
37	0.11

[1] 95th percentile of the maximum detected concentrations from surface water monitoring studies
[2] 95th percentile of the mean concentration for each study site including ½ LOD for non-detects
The monitoring data are presented in Table 4.

3.4 Drinking Water Exposure Estimates from Monitoring Data

As chlorothalonil is undergoing re-evaluation under Program 1 for the human health portion of the review, exposure estimates for drinking water using monitoring data were not generated. The monitoring data are summarized in Table 4.

4.0 Discussion and Conclusions

4.1 Discussion of Exposure Estimates for Ecoscenario

The concentrations of chlorothalonil in wetlands are reported as a range consisting as upper bound and lower bound concentrations rather than a discrete exposure value. The upper bound values are represented as the Level 1 EECs in wetlands, estimated by PRZM-EXAMS for the one-in-ten year exposure (or 90th percentile) (Tables 2 and 3). These upper bound concentrations represent the highest concentrations of chlorothalonil expected in surface water in Canada for the peak, 96-hour, 21-day, 60-day, 90-day, and 1 year time periods. Upper bound concentrations were reported for wetlands 80 cm and 15 cm deep.

The lower end of the range was derived from the available monitoring data on chlorothalonil and represents the acute and chronic concentrations of chlorothalonil in surface water in Canada (Table 4). No time frames other than acute and chronic could be calculated using the monitoring data. No region-specific EECs are provided. The lower bound acute and chronic exposure values were estimated from monitoring data using the 95th percentiles of the maximum and arithmetic mean concentrations (including non-detects) measured in each monitoring study/site, respectively.

The concentrations of chlorothalonil detected in water were obtained from studies conducted in various regions across the country. Most of the samples were analyzed in the 1990's and 2000's. Chlorothalonil was generally detected infrequently, and at low levels in most monitoring studies. The acute and chronic concentrations predicted by PRZM-EXAMS are generally higher than those determined by the monitoring data. This could be because water monitoring, as conducted in most of the studies reviewed, involves sampling that is limited in time and space and is unlikely to detect the true maximum concentration of the analyte in question. On the other hand, the models predict the concentration expected on a daily basis which allows for the determination of a peak (acute) concentration.

An exception to this would be found in the PSF (Pesticide Science Fund) monitoring data from the Atlantic provinces generated in 2006, 2007 and 2008. Sampling occurred during run-off/precipitation events, capturing peak concentrations of chlorothalonil in these locations. For example, in 2006, the maximum chlorothalonil concentration in water from sites in New Brunswick, was 312.1 µg/L at the 'Weir # 1' (Black Brook) site and 39.78 µg/L at the 'Weir # 12' (Little River) site. Also, in PEI, the maximum concentration of chlorothalonil in surface water during a precipitation event in 2008 was 32.38 µg/L. See Table 4 for summaries of the data and of the studies.

4.2 Discussion of Exposure Estimates for Drinking Water

The concentrations of chlorothalonil detected in potential drinking water sources were obtained from Canadian studies conducted in various regions across the country. Most of the samples were analyzed in the 1990's and 2000's (Table 4). Chlorothalonil was generally detected infrequently, and at low levels in most monitoring studies. This is because water monitoring, as conducted in most of the studies reviewed, involves sampling that is limited in time and space and is unlikely to detect the true maximum concentration of the analyte in question.

An exception to this trend would be found in the PSF monitoring data from the Atlantic Provinces generated from 2003 to 2008. Sampling occurred during run-off/precipitation events, capturing peak concentrations of chlorothalonil in those locations. For example, in 2006, the maximum chlorothalonil concentrations in water from a site on the Little River (Weir #12) in New Brunswick following run-off events was 39.78 µg/L. See Table 4 for summaries of the data and of the studies.

Appendix X Proposed Label Amendments for Products Containing Chlorothalonil

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

A. The Primary Display Panel of the labels of end-use products containing chlorothalonil must be amended to include Signal Words for eye irritation. A related precautionary statement must also be included on the secondary panel under PRECAUTIONS.

B. The labels of end-use products registered for use on agricultural crops, ornamentals, conifers, or turf must be amended to reflect the applications instructions12 outlined in Appendix XI.

C. The labels of Registration Number 15724 and 28354 must be amended to reflect the use directions outlined below:

I) For Registration Number 15724:

Disease	Interval of Application	RATE: Millilitres per 100 sq. Metres	
		Preventative*	Curative**
Dollar spot	7 – 14 days	95 – 190****	190****
Helminthosporium leafspot and melting out	7 – 10 days	95 – 190	190
Large brown patch	7 – 10 days	95 – 190	190
Anthracnose	7 – 10 days	170 – 190	not recommended
Grey snow mould (*Typhula incarnata*) and Pink snow mould (*Microdochium nivale*)	—	240***	not recommended

* Recommended rates for preventing disease establishment; use lower rate when disease conditions are light to moderate, higher indicated rates when conditions are severe.

** Rates for use on a 7 day schedule when disease is present.

*** Apply DACONIL 2787 Flowable Fungicide with 125 to 250 milliliters of ROVRAL® Green GT Fungicide per 100 sq. m prior to snow cover in the fall and repeat in the early spring if conditions for snow mould continue to exist.

**** Apply DACONIL 2787 Flowable Fungicide at 190 milliliters as a tank mix with 26 milliliters of Banner MAXX® Fungicide per 100 sq. meters and an interval of 21 – 28 days to control Dollar Spot.

12 The maximum single application rates indicated on product labels must not exceed the rates indicated in Appendix XI. However, current maximum single application rates on product labels cannot be increased based on the rate provided in Appendix XI. Product labels must be amended to indicate a maximum number of applications per year or production cycle, or a maximum annual rate, for each use site, which must not exceed the rates provided in Appendix XI. Product labels must be amended to indicate a minimum application interval for each use site, which must not be shorter than the application interval provided in Appendix XI.

II) For Registration Number 28354:

On Golf Course Tees, Greens, Fairways and Ornamental Turfgrass:
Apply DACONIL Ultrex Fungicide in an adequate amount of water to provide complete coverage. See table below for rates of product and application intervals. Apply DACONIL Ultrex Fungicide when conditions favor disease development and repeat applications as long as these conditions persist. Under severe disease conditions, use the curative rates and spray on a 7 day schedule.

Crop Group	Disease	Interval of Application	Rate: Grams of Product per 100 sq. Meters	
			Preventative	Curative
Fairways	Dollar spot	7 – 14 days	29 – 58	-
Golf Course Tees, Greens, Ornamental Turfgrass	Dollar spot	7 – 14 days	58 – 115	115
Golf Course Tees, Greens, Fairways, Ornamental Turfgrass	Helminthosporium leafspot and melting out	7 – 14 days	58 – 115	115
	Brown patch	7 – 14 days	58 – 155	115
	Anthracnose	7 – 10 days	103 – 115	Not recommended
	Gray snow mould (*Typhula incarnata*) and Pink snow mould (*Microdochium nivale*)	–	145	Not recommended

Dollar Spot Control: Under severe disease conditions, apply DACONIL Ultrex Fungicide at a rate of 115 g/100 m2 as a tank mix with Banner MAXX Fungicide at rate of 30 ml/100 m2.

Snow Mould Control: Apply DACONIL Ultrex Fungicide at a rate of 145 g/100 m2 as a tank mix with ROVRAL Green GT at a rate of 125 to 250 ml/100 m2 prior to snow cover in the fall and repeat in the early spring if conditions for snow mould continue to exist.

D. The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in a section entitled **PRECAUTIONS** for those products that are registered for agricultural use, use on turf, or use on ornamentals, in addition to any personal protective equipment already present on the labels:

Mixers, loaders, applicators and all other handlers must wear a long-sleeved shirt, long pants and protective eyewear. In addition, chemical-resistant gloves must be worn by: (1) mixers/loaders, (2) other handlers exposed to the concentrate, (3) cleaners/repairers of equipment, (4) applicators using airblast equipment for golf course applications, and (5) applicators using hand-held equipment. In addition, either a respirator with a NIOSH/MSHA/BHSE-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH/MSHA/BHSE-approved canister approved for pesticides must be worn by applicators and other handlers in enclosed areas such as greenhouses and mushroom houses, and handlers using a high-pressure hand-wand.

II) The following statement must be included in a section entitled **PRECAUTIONS** for those products that are registered for agricultural use or use on conifers and ornamentals (including greenhouses and mushroom houses):

DO NOT re-enter treated areas within 48 hours. If required, individuals may re-enter treated areas within 48 hours for short-term tasks not involving hand labour only if at least 4 hours have passed since application, and long pants, long-sleeved shirt, hat, protective eyewear and chemical-resistant gloves are worn.

III) The following statement must be included in a section entitled **PRECAUTIONS** for those products that are registered for use on turf:

DO NOT enter or allow entry into the treated area until spray has dried.

IV) The following statement must be included in a section entitled **PRECAUTIONS** for those products that are registered for commercial application to control mildew on paint film:

All handlers must wear protective eyewear, a long-sleeved shirt, long pants, chemical-resistant gloves and either a respirator with a NIOSH/MSHA/BHSE-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH/MSHA/BHSE-approved canister approved for pesticides.

V) The following statements must be included in a section entitled **DIRECTIONS FOR USE** for products registered for commercial application to control mildew on paint film:

This product may only be added to paint products that are labelled (a) with product-specific instructions for the use of a respirator during application, or (b) as follows "When applying with a sprayer, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH-approved respirator with any R, P, or HE filter. If oil is not present in the paint product or recommended for use as an additive in the paint product, add "N" as an additional respirator type."

VI) The following statement must be removed from the label of all products registered for commercial application to control mildew on paint film:

Use protective barrier cream on exposed skin areas.

VII) The following statement must be included in a section entitled **DIRECTIONS FOR USE** for products registered for agricultural use, or use on conifers, ornamentals, or turf:

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer*	Potato		2	1	2	1
	Cole crops, cucurbits, onions, carrots, parsnip, sweet corn, celery, chickpeas, lentils, dry peas, wheat, tomatoes, ginseng, strawberries, evening primose, asparagus, ornamentals		4	1	4	2
	Conifers, lowbush blueberries		5	1	5	3
	Cranberries		10	1	10	4
	Turf (including golf greens, tees and fairways, and sod farms)		15	2	15	5
Airblast	Ornamentals	Early growth stage	35	10	35	25
		Late growth stage	25	5	25	15
	Stone fruit, highbush blueberries, conifers	Early growth stage	40	15	40	30
		Late growth stage	30	10	30	20

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Aerial	Potato, evening primrose	Fixed wing	70	5	70	20
		Rotary wing	50	1	50	15
	Dry peas, wheat	Fixed wing	100	5	100	25
		Rotary wing	70	4	70	20
	Carrots, parsnips, sweet corn	Fixed wing	100	10	100	30
		Rotary wing	75	5	75	25
	Celery, lentils	Fixed wing	175	10	175	45
		Rotary wing	100	5	100	30
	Onions, ginseng, tomatoes	Fixed wing	200	10	200	60
		Rotary wing	125	10	125	40
	Stone fruit	Fixed wing	225	15	225	100
		Rotary wing	150	10	150	65
	Blueberry	Fixed wing	250	15	250	95
		Rotary wing	150	10	150	60

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

VIII) The following statement must be included in a section entitled **DIRECTIONS FOR USE** for products registered for use on greenhouse ornamentals:

For use on greenhouse cut flowers, **DO NOT** exceed 4 applications per floral production cycle. For use on greenhouse conifers or potted ornamentals, **DO NOT** exceed 4 applications per crop production cycle.

IX) The following statement must be included in a section entitled **DIRECTION FOR USE** for products registered for agricultural uses, including celery seedbeds:

DO NOT use on greenhouse-grown agricultural crops, with the exception of celery seedbeds.

X) The following statement must be included in a section entitled **DIRECTION FOR USE** for products registered for agricultural uses, excluding celery seedbeds:

DO NOT use on greenhouse-grown agricultural crops.

XI) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS** for products registered for agricultural use, or use on conifers, ornamentals, or turf:

TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce run-off from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of run-off may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Appendix XI Proposed Canadian Application Instructions

Table 1 Proposed Canadian Application Instructions for Agricultural crops

Crop	Maximum Single Application Rate (kg a.i./ha)	Maximum Number of Applications Per Year	Minimum Application Interval (days)
Asparagus	1.7	3	14
Blueberry – lowbush, (for the control of Phomopsis canker and leaf spot diseases)	3.6	2	Early to mid-June Early August
Blueberry	3.6	3	Green tip Pink bud Petal fall
Carrot	1.6	7	7
Celery	2.0	9	8
Chickpea	2.0	3	10
Cole crops	2.4	5	7
Cranberry	5.8	3	10
Cucurbits	2.4	7	7
Dry Peas	1.5	3	10
Evening primrose	1.2	2	14
Ginseng	2.4	6	7
Lentils	2.0	2	10
Mushroom	127 g/100m^2	2 (per crop production cycle)	-
Onion, dry bulb	2.4	3	7
Onion, green	2.4	5	7
Parsnip	1.4	7	7
Potato	1.2	12	7
Strawberry	1.75	3	10
Stone fruits	4.5	4	Specific stages on label
Sweet corn	1.6	2	10
Tomato	2.4	9	8
Wheat	1.25	3	10

Table 2 Proposed Canadian Application Instructions for Ornamentals and Conifers

Crop	Maximum Single Application Rate (kg a.i./ha)	Maximum Number of Applications Per Crop (or Floral) Production Cycle	Minimum Application Interval (days)
Outdoor			
Conifers	4.75	4	7
Ornamentals	2.5	23	7
Greenhouse			
Conifers	4.75	4	7
Cut flowers	2.5	4	7
Potted ornamentals	2.5	4	7

Table 3 Proposed Canadian Application Instructions for Turf Uses

Use site	Maximum Single Application Rate[1] (Minimum Application Interval)	Maximum Annual Application Rate (kg a.i./ha)
Greens	12.00 kg a.i./ha (one application)[2] 9.54 kg a.i./ha (14-day interval) 4.75 kg a.i./ha (7-day interval)	81.76
Tees	12.00 kg a.i./ha (one application)[2] 9.54 kg a.i./ha (14-day interval) 4.75 kg a.i./ha (7-day interval)	58.24
Fairways	12.00 kg a.i./ha (one application)[2] 9.54 kg a.i./ha (14-day interval) 4.75 kg a.i./ha (7-day interval)	58.24
Sod Farm	12.66 kg a.i./ha (one application)[2] 9.54 kg a.i./ha (7-day interval)	29.12

[1] The maximum single application rate varies depending on the disease.
[2] For Registration Number 15724 and 28354, refer to Appendix X for specific label statements proposed for use directions for snow mould control.

Appendix XII Inputs to Buffer Zone Models

Table 1 Ground Use Data (from Canadian labels)

Crop	Formulation Type	Method of Application	Number of Application	Maximum Application Rate (g a.i./ha)
Golf course - fairways	Soluble concentrate	Field (medium)	5	12 660
Stone fruits	Soluble concentrate	Early airblast	4	4 500
Stone fruits	Soluble concentrate	Late airblast	4	4 500
Highbush blueberries	Soluble concentrate	Early airblast	3	3 600
Highbush blueberries	Soluble concentrate	Late airblast	3	3 600
Potatoes	Soluble concentrate	Field (medium)	10	1 200

Table 2 Model Input Data for Aquatic Buffer Zones

Half-life for aquatic buffer zones	Aerobic whole system	0.5 days
Most sensitive amphibian species	Japanese common toad	1/10 LC_{50} = 0.016 mg a.i./L
Most sensitive freshwater species	Freshwater fish	LC_5 = 0.013 mg a.i./L
Most sensitive estuarine/marine species	Three spine stickleback	1/10 LC_{50} = 0.003 mg a.i./L

Table 3 Aerial Use Data (from Canadian Labels)

Crop	Formulation Type	Registration No.	Number of Applications	Rate of Application (g a.i./h)
Stone fuits	Soluble Concentrate	15723	4	4 500
Stone fuits	Soluble Concentrate	29225	4	4 500
Highbush blueberries	Soluble Concentrate	15723	3	3 600
Highbush blueberries	Soluble Concentrate	29225	3	3 600
Potatoes	Soluble Concentrate	15723	10	1 200
Potatoes	Soluble Concentrate	29225	10	1 200

Table 4 Product Information for Aerial Use

Parameter	Value
Registration No. 15723	
Aircraft type	Fixed or rotary wind
ASAE spray quality	Crop (medium)
Carrier	Water
Product guarantee (g a.i./L)	500
Specific gravity of end-use product (g/ml)	1.24
Minimum spray volume (L/ha)	50
Water content of product (%)	51
Wind speed (km/h)	16
Temperature (°C)	25
Relative humidity (%)	50
Registration No. 29225	
Aircraft type	Fixed or rotary wind
ASAE spray quality	Crop (medium)
Carrier	Water
Product guarantee (g a.i./L)	720
Specific gravity of end-use product (g/ml)	1.36
Minimum spray volume (L/ha)	50
Water content of product (%)	35
Wind speed (km/h)	16
Temperature (°C)	25
Relative humidity (%)	50

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